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ORIGINAL SUBMISSION

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February 18, 1999

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Office of Premarket Approval
HFS-200
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, D.C. 20204

1999 FEB 19 P 12: 48

**Re: GRAS Exemption Claim for Tasteless Smoke**

To Whom it May Concern:

On behalf of our client, Hawaii International Seafood Inc., Honolulu International Airport, P.O. Box 30486, Honolulu, Hawaii 96820, we submit this notification which contains data and information establishing that tasteless smoke is generally recognized as safe (GRAS). We enclose an original and two copies of this notification for your review.

Tasteless smoke is used to protect the taste, aroma and color of seafood at levels sufficient to accomplish this purpose. Tasteless smoke is merely a purified version of the filtered smoke that has been used for decades in the processing of seafood. Data in this submission establish that tasteless smoke is GRAS on the basis of scientific procedures and common use in foods. Because tasteless smoke is GRAS, it is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act. Additional data and information supporting the GRAS status of tasteless smoke, including the raw data, will be made available for the Food and Drug Administration (FDA) review upon request.

As you may recall, Hawaii International Seafood originally submitted a notification for tasteless smoke in April 1998. That notification contained confidential business information (CBI). We recognize that the inclusion of confidential information in that notification presented numerous issues. In our letter of November 9, 1998 we asked the agency to suspend its review of that submission. The enclosed submission differs from our original submission in that it does not include any CBI. In addition, the enclosed submission contains data and information collected since our original submission that further support the GRAS status of tasteless smoke. Hawaii International Seafood collected much of these data in response to questions raised by the agency in its review of the earlier submission.

If you have any questions, please contact me at the above phone number and address.

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Enclosures

Hawaii International Seafood, Inc.
GRAS Notification Summary
For the Use of Tasteless Smoke
In the Preservation of Seafood
February **1999**

# I. DESCRIPTION OF THE SUBSTANCE

## A. Common **or** Usual Name

The common or usual name is tasteless smoke. Tasteless smoke is an appropriate name because the product is manufactured by filtering conventional smoke. Tasteless smoke is generated by combusting wood chips in contact with a heated surface, capturing the smoke and running it through a filtration and purification process that removes the particulate matter and many of the flavor components found in conventional smoke. Tasteless smoke is merely a super-filtered version of the conventional smoke that has been used for decades in the cold-smoking of fish.

## **B.** Chemical Name

There are numerous chemicals in tasteless smoke just as there are numerous different chemicals in smoke. The primary components in tasteless smoke are nitrogen ($N_2$), oxygen ($O_2$), carbon monoxide (CO), carbon dioxide ($CO_2$), methane ($CH_4$), aromatic phenols and hydrocarbons.

## C. CAS Number

There is no **CAS** number for tasteless smoke.

## D. Empirical Formula

There is no empirical formula for tasteless smoke per se. There are, however, empirical formulas for the constituents found in tasteless smoke. For example, the primary components in tasteless smoke are nitrogen ($N_2$), oxygen ($O_2$), carbon monoxide (CO), carbon dioxide ($CO_2$), and methane ($CH_4$). There are also trace levels of different aromatic phenols and hydrocarbons.

## **E.** Structural Formula

There also is no structural formula for tasteless smoke per se. As discussed, above, there are structural formulas for the primary components in the tasteless smoke (*i.e.,* nitrogen ($N_2$), oxygen ($O_2$), carbon monoxide (CO), carbon dioxide ($CO_2$), and methane ($CH_4$)).

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## F. Specifications **for** Food Grade Material

The following specifications are established for the tasteless smoke:

| | |
|---|---|
| Carbon Dioxide | 7-25% |
| Carbon Monoxide | 7-30% |
| Aromatic Phenols (gaseous vapor) | 10 ppb to 15.6 ppm |
| Hydrocarbons ($C_5$ to $C_{10}$) | 2000 to 6000 ppm (volume) |
| Hydrocarbons ($C_2$ to $C_4$) | 2000 to 6000 ppm (volume) |
| Combustion Temperature | <850 °F |

The specification for the combustion temperature has been established to reduce the formation of deleterious compounds in the smoke. The form'ation of deleterious polynuclear aromatic hydrocarbons (PAHs) and the oxidation of organic vapors, including both condensable organic compounds as well as volatile organic compounds (VOCs) can be prevented by combusting below 850 °F (454 °C). Although most of these VOCs are removed by the filtration and purification process, the 850 °F specification is nonetheless established to minimize the formation of these undesirable compounds.

## *G.* Quantitative Composition

Tasteless smoke has the following quantitative composition:

| | |
|---|---|
| Carbon Dioxide | 7-25% |
| Carbon Monoxide | 7-30% |
| Aromatic Phenols (gaseous vapor) | 10 ppb to 15.6 ppm |
| Hydrocarbons ($C_5$ to $C_{10}$) | 2000 to 6000 ppm (volume) |
| Hydrocarbons ($C_2$ to $C_4$) | 2000 to 6000 ppm (volume) |
| Nitrogen and Oxygen | 45-86% |
| Methane | <15% |

## H. Manufacturing Process

Smoke is generated by burning an organic, food grade smoking material below 850 °F (454 °C) in a smoke generator. This conventional smoke is then passed through **a** proprietary filtration process. This filtration process removes the particulate matter and the taste components from the vapor phase of the smoke. The filtered smoke is then allowed to flow directly into a smoking chamber or it is collected and stored for use at a later time.

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The seafood is placed in a smoking chamber where the temperature is maintained just slightly over freezing. 1/ The chamber is flooded with tasteless smoke and the seafood will remain in the smoking chamber until the smoke has had sufficient time to penetrate the tissue and impart its preservative effect. The "smoking" time will vary depending on several factors such as the species, type of cut and thickness of the cut. Through the expenditure of considerable resources, Hawaii International Seafood has developed an internal data base that identifies the amount of time a particular cut of seafood needs to be exposed to the tasteless smoke. Hawaii International Seafood developed this data base by exposing cuts of the seafood to tasteless smoke for different times. Hawaii International Seafood performed organoleptic and other evaluations of the product to assess how much time is needed for the tasteless smoke to impart its preservative characteristics.

After the product has been exposed to the tasteless smoke for the requisite amount of time, it is removed from the smoking and cryogenically frozen. The tasteless smoke treated seafood can be stored for up to one year. The treated product can be quick or slow thawed with little degradation of the taste, aroma, texture or color of the treated seafood.

## 11. USE OF TASTELESS SMOKE

### A. Date When Use Began

#### 1. Conventional Smoke Has Been Used for Centuries

Smoke has been used for centuries in the preservation of seafood. The preservation effect came from not only the components in the smoke, but also from the heating and drying associated with the smoking process. With the advent of refrigeration, the use of smoke as the primary means to preserve seafood became less important, although smoked seafood continues to have a longer shelf life than their non-smoked counterparts.

#### 2. Filtered Smoke Has Been Used for at Least 90 Years

Tasteless smoke is derived by filtering and purifying conventional smoke. Meat and seafood processors have been using purified smoke for at least 90 years. A 1908 U.S. patent discusses a device for curing edible matter comprised of a curing compartment, a smoke supply source, and a combined smoke cooling, purifying, and drying chamber where a portion of moisture and carbon soot

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1/ Seafood can be maintained fresh and unfrozen for two to three weeks at temperatures of **27** to **32 °F (-0.3** to 0°C). It does not freeze at these temperatures due to the salt content in the meat.

condenses on the walls of the chamber. 2/ This method and apparatus manufactures purified smoke with substantially all odor and taste imparting particulate matter removed from the particulate phase of the smoke leaving only odor and taste imparting vapors.

In addition, many meat and seafood processors have used a number of systems to eliminate substantially all of the particulate matter from smoke. The pollutants in the particulate phase of smoke are typically filtered. Many methods are used to filter out the tar, soot, ash, char and other microscopic particulates, such as tar settling systems, baffling systems, and washing systems in the line from the smoke generator to the smoking chamber. In addition, cooling and storage reduces the concentrations of phenolic particulate through settling. Some of these filtering methods remove substantially all the tar and particulate from wood smoke leaving only the gaseous vapor phase which produces the characteristic smoke flavor. The amount of particulate mattered filtered from the smoke can range from 0 to **100%.** This filtered smoke has been used to treat seafood since well before **1958.**

### 3. Filtered Smoke Has Been Used on Raw Fish at Cold Temperatures for Over 70 Years

Fish has been both hot and cold smoked for generations. A purified smoke has been used to cold smoke salmon in Europe and North America for decades. Salmon is treated with the purified smoke to preserve its color and texture and to impart a light smoke taste. Tasteless smoke is a super-filtered version of the same smoke that has been used in salmon smoke houses for decades.

Although it is difficult to state precisely when the fish industry first used the cold smoking process, our review has established that this process has been practiced for at least 70 years. For example, in the U.S. Pacific Northwest, Josephson's Smokehouse & Specialty Seafood Company has been cold smoking high quality Pacific Chinook Salmon since **1920.** In Oregon, Sportsmen's Cannery & Smokehouse, established in **1955,** utilizes a cold smoked process. In California, the Los Angeles Smoking & Curing Company (LASCCO) has been cold smoking seafood since **1921.** All three of these examples of cold smoking of salmon prior to **1958** show the use of purified wood smoke to fix salmon color and texture. In addition, Josephson's and LASCCO have cold smoked albacore tuna as well. 3/

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2/ U.S. Patent 889,828 to Trescott **(1908).**

3/ *See* Appendix **1** for testimonials which establish that seafood companies have cold-smoked fish prior to **1958.**

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### B. Conventional Smoke is GRAS

Conventional smoke is generally recognized as safe (GRAS). Although FDA has not specifically listed or affirmed it as GRAS, FDA is not required to do so under the Federal, Food, Drug and Cosmetic Act. Indeed, FDA specifically recognizes in its GRAS regulations that it is "impracticable to list all substances that are generally recognized as safe for their intended use." 4/ The GRAS status of conventional smoke is supported by the numerous food standards and other FDA regulations that specifically recognize the use of smoke as an ingredient in foods. For example, the standard of identity for canned tuna specifically allows the product to be smoked. 5/

In addition, there are numerous cheese standards of identity that specifically authorize for the smoking of cheese, including the standards for colby cheese, cold-pack cheese, cold-pack cheese food, pasteurized process cheese, pasteurize process cheese food, pasteurized process cheese spread, and provolone. 6/ The GRAS status of conventional wood smoke is further supported by its listing as an approved ingredient that may be added to meat and poultry products. 7/

### C. Tasteless Smoke is Substantially Equivalent to Forms of Smoke that Have Been Used Prior to 1958

Tasteless smoke is substantially equivalent to conventional smoke. There is tremendous variability in the composition of smoke and the components of tasteless smoke are within ranges ordinarily found in conventional smoke. The source of the wood, the combustion temperature, the amount of oxygen in the combustion chamber, and the filtration process, if any, are examples of the factors that will have an impact on the final composition of wood smoke. A publication of the Environmental Protection Agency (EPA) demonstrates the tremendous variability in the composition of wood smoke, particularly with regard to the levels of carbon monoxide and carbon dioxide. 8/ This publication identifies the various components in smoke and reports the grams of such components produced from one kilogram of wood. The chart below compares the amount of carbon monoxide and

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4/ 21 CFR § 182.1(a).

5/ 21 CFR § 169.190(a)(3)(v).

6/ 21 CFR § § 133.118(d)(1), 133.123(b)(1), 133.124(b), 133.169(b), 133.173(b), 133.17500) and 133.181(a)(3), respectively.

7/ 9 CFR §§ 318.7(c)(4), 381.147(c)(4).

8/ See Appendix 2.

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carbon dioxide generated from one kilogram of wood in conventional and tasteless smoke:

| | **Tasteless Smoke** | | **Conventional Smoke** | |
|---|---|---|---|---|
| **Carbon Monoxide** | **15-66** g/kg wood | | 80-370 g/kg wood | |
| **Carbon Dioxide** | **15-55** g/kg wood | | *70-200* g/kg wood | |
| **Ratios CO/CO2** | **Low Range** | **High Range** | **Low Range** | **High Range** |
| | **1** | 1.1 | 1.1 | 1.85 |

This table demonstrates that the manufacturing process for tasteless smoke has not been altered to increase the carbon monoxide or carbon dioxide emissions in the finished product. These data demonstrate that the levels of carbon monoxide and carbon dioxide generated from one kilogram of wood are actually less than that generated in conventional smoke. This difference is likely attributable to the controlled, proprietary conditions under which the wood is combusted.

In addition, a comparison of the carbon monoxide/carbon dioxide ratios reviews that tasteless smoke actually contains a lower percentage of carbon, monoxide than conventional smoke. There is a tremendous variability in the carbon monoxide and carbon dioxide concentrations of both tasteless and conventional smoke. On the lower end of this range, both tasteless smoke and conventional smoke have essential equal quantities of carbon monoxide and carbon dioxide. On the upper end of the range, however, conventional smoke can have up to **1.85** times the level of carbon monoxide than carbon dioxide while tasteless smoke has comparable levels of carbon monoxide and carbon dioxide. The carbon monoxide content'of tasteless smoke, therefore, has not been increased through the manufacturing process.

Also worth mentioning is that the above chart provides compositional information on unfiltered, conventional smoke. Tasteless smoke is even closer in composition to the filtered smoke which has been used for decades in the seafood industry. The process used to manufacture tasteless smoke is comparable to that used to manufacture filtered smoke except the smoke continues to run through additional filters that remove additional quantities of the same components that are removed from filtered smoke. It is estimated that the manufacturing process for tasteless smoke removes only 0.07 percent, by weight, of the components found in filtered smoke.

### D. The Components of Tasteless Smoke and Conventional Smoke are Found in Comparable Levels in Seafood Treated with These Products

Seafood treated with tasteless and conventional smoke have comparable levels of carbon monoxide, carbon dioxide, aromatic phenols, and hydrocarbons. Hawaii International Seafood smoked Albacore, Salmon, and Yellowfin with conventional smoke and tasteless smoke. An independent laboratory analyzed the products and the results of this analysis can be found in Appendix **3.**

These data show significant differences in carbon monoxide and carbon dioxide levels in samples subjected to identical conditions. For example, the quantity of carbon dioxide found in Albacore treated with tasteless smoke ranged from approximately 2400 to 7900 and the quantity of carbon dioxide found in Salmon treated with raw smoke ranged from approximately 5,000 to 16,000. The levels of carbon monoxide in Albacore treated with tasteless smoke ranged from 19 to 24 while the levels found in conventionally smoked Albacore ranged from **23** to 52. These data reveal that the seafood treated with tasteless smoke and conventional smoke had comparable levels of carbon monoxide, carbon dioxide, $C_2$ to $C_4$ hydrocarbons, and phenols. The results did show slightly higher levels of the $C_4$-$C_{10}$ hydrocarbons in the tasteless smoke treated products, but a statistical analysis revealed no significant difference in these numbers. The use of tasteless smoke, therefore, is expected to result in levels of carbon monoxide, carbon dioxide, hydrocarbons and phenols comparable to that found in seafood treated with conventional smoke.

### E. Tasteless Smoke is GRAS Based on Common Use in Foods and Scientific ,Procedures

Tasteless smoke is GRAS based on common use in foods and scientific procedures. Data in this notification demonstrate that tasteless smoke is manufactured and used in a manner consistent with practices that have been used by the seafood industry for many years prior to 1958. Tasteless smoke is generated from wood--the same starting material used to make conventional smoke which is undeniably a GRAS ingredient. Tasteless smoke also has a composition that is substantially equivalent to the composition of conventional smoke. There is a tremendous variability in the composition of conventional smoke and the data in this notification establish that the primary constituents of tasteless smoke are within or below this "normal range."

Filtered smoke has been used in the seafood industry prior to 1958. Tasteless smoke is manufactured by subjecting filtered smoke to another filtration step. The filtration step used by Hawaii International Seafood removes the same constituents that are removed during the conventional filtration process, although they are removed to a greater degree. This filtration step removes only 0.07 percent, by weight, of the taste- and odor-imparting chemicals found in the filtered smoke. Nothing is added to the tasteless smoke (except air--which is also found in conventional smoke). These compositional similarities establish that tasteless smoke is substantially equivalent to filtered smokes.

The application of tasteless smoke at refrigerated temperatures is also consistent with a pre-1958 practice. Seafood processors have smoked tuna and salmon at refrigerated temperatures using filtered smoke for at least 70 years. One of the intended uses of cold smoking is to preserve the taste, aroma and texture of the product. Tasteless smoke is applied in a similar manner and for this very intended use. In addition, the data demonstrate that carbon monoxide, carbon dioxide, phenols and hydrocarbons (*i.e.,* the components of tasteless smoke for which specifications are established) in seafood that is treated with tasteless smoke are found at comparable levels as seafood that is cold-smoked with conventional smoke.

### 1. Experts Have Reviewed the Data on Tasteless Smoke and Concluded that it is GRAS

Dr. Joseph Maga, Director of the Department of Food Science and Human Nutrition at Colorado State University has reviewed the tasteless smoke process and concluded that tasteless smoke is GRAS. Dr. Maga offered the following comments in this regard:

> The use of various smoke preparations (smoke vapor, liquid smoke extracts) have been routinely used in food preparation for centuries / decades. In most operations the particulate phase in both gaseous and liquid smoke preparations is routinely removed by various physical means such as filtration, sedimentation, and electrostatic precipitation to name a few. Your "Tasteless" smoke purification is simply an extension of traditional smoke purification. The resulting product does not have anything added and all components present in the product were originally present in smoke.

Additional experts in the area of smoking technology also have reviewed the process and concluded that tasteless smoke is G U S . The letters from these experts can be found in Appendix **4.** The names, addresses and titles of the experts who have reviewed the process and concluded that tasteless smoke is G U S are identified below:

Dr. Joseph Maga
Director
Department of Food Science and Human Nutrition
Colorado State University
Fort Collins, Colorado **80523-1571**

Dr. Steven D. Hoyt
President
Environmental Analytical Services, Inc.
**3421** Empresa, Suite A
San Luis Obispo, California **93401**

Robert Hanson
Technical Director
Alkar, Inc.
**932** Development Drive
P.O. Box **260**
Lodi, Wisconsin **53555**

**2. Tasteless Smoke Does Not Present the Potential Health Risks of Conventional Smoke Because the Carcinogenic Impurities Are Filtered Out and Removed**

Tasteless smoke does differ from unfiltered conventional smoke in that all of the particulate matter and most of the flavor- and odor-imparting components have been removed. Also removed from tasteless smoke are the highly toxic and potentially carcinogenic compounds found in conventional smoke.

FDA recognizes that conventional smoke can be a source of carcinogenic impurities such as Benzo[a]pyrene (BaP) and other polynuclear aromatic hydrocarbons (PAHs). 9/ Tasteless smoke does not present the same potential health risks of conventional smoke because carcinogenic impurities are filtered out and removed. The super-purifying process of producing tasteless smoke removes any remaining particulate matter from the particulate phase and reduces the phenolic level of the gaseous phase below the odor and taste threshold. 10/

## F. Intended Use

The tasteless smoke is intended to be used on raw seafood, such as tuna and salmon, before it is frozen. The tasteless smoke is added to preserve the taste, aroma, texture and color of the frozen seafood. As will be discussed in more detail below, without the addition of tasteless smoke, frozen tuna and other red-

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9/ Food Additives Analytical Manual -- Volume II, "Polynuclear Aromatic Hydrocarbons" **(1987).**

10/ The odor threshold for the vapor in smoke is 10.4ppm, while the taste threshold is **2.3** ppm. Daun, H., Lebensm, Wiss. Technol. **5,102 (1972).**

meat seafood is prone to browning, the development of off odors and decreased palatability during freezing.

### G. Limitations

There are no limitations on the use of tasteless smoke other than those imposed by good manufacturing practices. Hawaii International Seafood does limit the use of tasteless smoke to higher grades of tuna (*i.e.,* Japan B grade for frozen sashimi tuna and No. **1** U.S. cooking grade for frozen tuna steaks). This limitation assures that only higher quality tuna will be subjected to treatment with tasteless smoke. In addition, the grade of the tuna that is treated with the tasteless smoke is declared voluntarily on the label of the product.

## 111. EFFICACY DATA

### A. Background

#### 1. Color Physiology

The pigments in meat and in some species of seafood, such as tuna, consist largely of two proteins: hemoglobin, the pigment of the blood, and myoglobin, the pigment of the muscles. In well bled muscle tissue, up to 80 to 90 percent of the total pigment is myoglobin. The myoglobin molecule contains a globular protein portion (*i.e.,* globin) and a nonprotein heme ring. The heme ring contains an iron ion. The color of the heme ring and of the myoglobin molecule, is partially dependent on the oxidative state of the iron within the heme ring.

The quantity of myoglobin within the tissue and the intensity of the color varies depending on species, age, sex, muscle and physical activity. Species differences are apparent when comparing the lighter color of swordfish with the dark red color of tuna or the lighter color of pork with the darker color of beef. The impact of age is most apparent by comparing the lighter color of veal with the darker color of beef. There are also differences within species in that some tuna will have a higher quantity of myoglobin in the muscle tissue than other tuna. These intraspecies differences account for the variability in color of tuna steaks that are cut from different fish.

The color of the meat is affected by the quantity of myoglobin in the tissue and by the oxidative state of the iron in the myoglobin. When the meat is first cut, the flesh has a dark red almost purple color, which is the color of myoglobin. The myoglobin easily reacts with the oxygen in the air and forms oxymyoglobin which has a bright red color. When the oxymyoglobin is held in a conventional frozen environment, the iron ion in it is prone to oxidation and forms metmyoglobin, which has an undesirable brown color. The oxidized iron can also adversely effect the taste and smell of the product in that it leads to the oxidation of unsaturated fatty acids in seafood, thus generating volatile organic compound gases that produce undesirable smells and flavors.

The myoglobin can combine with substances other than oxygen and form compounds that are more stable at conventional frozen temperatures than oxymyoglobin. Of primary importance here are the reactions between myoglobin and the components in conventional smoke and tasteless smoke, carbon monoxide, nitric oxide, and nitrogen dioxide. In the presence of smoke and tasteless smoke, the myoglobin will form carboxymyoglobin, nitric oxide myoglobin, or nitrogen dioxide myoglobin, all of which are red.

The common curing agents, nitrates and nitrites, are sources of nitric oxide and lead to the formation of nitric oxide myoglobin. Curing a product with nitrates fixes color and preserve freshness, in part, by preventing oxidation of the oxymyoglobin into metmyoglobin. It is the FDA position that substances which "fix" or stabilize an existing color rather than add new colors are not color additives. This position is well settled and has been upheld by the courts. 11/

### 2. Impact of Freezing on Color of Fish

Freezing has an adverse impact on the color of tuna and other species of fish. The environment of conventional freezers with temperatures between 0 and -30°F (-18to -34° C) facilitates the development of metmyoglobin in frozen tuna and other species. Observable browning in frozen tuna is generally noticed after two months of freezing. 12/ The oxidation of the oxymyoglobin into metmyoglobin decreases the acceptability of the frozen tuna because of the undesirable off-brown color and of the off-odors that develop. Consequently, frozen red meat fish distributed in the United States is prone to the adverse effects of oxidation unless it has been treated to prevent such oxidation.

The oxidation of the oxymyoglobin can be prevented by maintaining the frozen seafood at super cold freezing temperatures below -76 °F. The use of these super cold temperatures is common in Japan which has an infrastructure that utilizes super cold freezers in the manufacturing and distribution system. Holding sashimi tuna at these super low temperatures is very effective in maintaining the natural bright red color of the flesh for up to one year. This technology is not widely

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11/ ***Public Citizen** v. **Hayes***, Food Drug Cosm. L. Rep. (CCH) ¶ 38,161 (D.D.C. 1982) (nitrites "fix" the red color of meats and therefore are not color additives).

12/ Maga, Color Properties Test Results for Untreated Two Month Frozen and Thawed Tuna Samples (Appendix 5).

utilized in the United States and the current processing and distribution channels lack the capabilities to maintain seafood at temperatures below -76 °F. Given the prohibitively expensive investment needed to upgrade the freezers and the undesirable color, taste and aroma of tuna that has been frozen for over two months, the U.S. seafood industry has been limited to using fresh seafood for sashimi and either fresh or frozen seafood with an undesirable color and flavor for cooking.

### 3. Benefits of Conventional Smoke and Tasteless Smoke

The components in conventional smoke fix the color of the seafood by reacting with the myoglobin to form compounds that are more stable at conventional frozen temperatures than oxymyoglobin. The carboxymyoglobin, nitric oxide myoglobin and nitrogen dioxide myoglobin form when conventional smoke is used to treat seafood. Because these forms of myoglobin are much more stable in a conventional freezer environment than oxymyoglobin, frozen smoked seafood will not experience the browning that is associated with its unsmoked counterpart.

Conventional smoke, however, imparts a characteristic smoke flavor which impacts the taste of the seafood product. The smoke taste makes conventional smoking an undesirable process for preserving the color, taste, texture and aroma of frozen seafood. Tasteless smoke provides a desirable alternative because it offers the preservative benefits of conventional smoke without the conventional smoke taste.

The treatment with tasteless smoke, like conventional smoke, results in the formation of carboxymyoglobin, nitric oxide myoglobin and nitrogen dioxide myoglobin. Unlike oxymyoglobin, these compounds are more stable in a frozen environment and do not lead to the formation of metmyoglobin or facilitate the oxidation of unsaturated fatty acids which generate off odors. It is important in cold smoking to keep the meat raw and uncooked to maximize the amount of vital cells available for this reaction.

. For example, salmon that is cold smoked using purified wood smoke and vacuum packed can be refrigerated for several months without any decomposition or development of off odors. Similarly, tasteless smoke treated tuna can be frozen for several months without any decomposition or undesirable "freezer" smells. The organoleptic "sniff test" shows significant retardation of decomposition of cold smoked product high in carboxymyoglobin.

## B. Tasteless Smoke Has a Preservative Effect on the Taste and Texture of Frozen Tuna

One of the most important qualities of a food is its taste. Texture and aroma are primary attributes of taste and tests have demonstrated that tasteless smoke has a preservative effect on the texture and aroma of treated products.

### 1. Tasteless Smoke Preserves Texture

Tasteless smoke has been demonstrated to increase the tenderness of raw and cooked tuna that have been frozen and thawed when compared to untreated frozen and thawed tuna. Dr. Maga states that:

> Toughness deals with resistance of fibular protein to cutting where as firmness deals with resistance to pressure, including setting back. Cooking will denature protein making it tougher. More protein/myoglobin denaturation would occur in untreated flesh than treated thereby influencing toughness. Tenderness would be considered to be its attribute because it would be associated with product juiciness.

Dr. Maga performed the texture analysis by using an Allo-Kramer shear press to measure textural properties of random samples from within each group for both raw and cooked (broiled) product. Three groups were tested: (1) tuna treated with tasteless smoke, (2) tuna treated with raw smoke, and (3) untreated tuna. The tuna were frozen and stored for either two or six months. The larger the number, the tougher the product. Conversely the smaller the number the more tender the product. 13/ The following table summarizes these results:

**Texture Results for Raw and Cooked Tuna**

| | **Frozen for 2 Months** | | **Frozen for Six Months** | |
|---|---|---|---|---|
| | **Raw** | **Cooked** | **Raw** | **Cooked** |
| Untreated | 6.91 | 7.23 | 6.53 | 6.90 |
| Tasteless Smoke Treated | 6.60<br>6.33 | 6.98<br>6.57 | 6.28 | 6.63 |
| Conventional Smoke | 6.37 | 6.60 | N.A. | N.A. |
| **N.A.** = Not **Analyzed** | | | | |

These results show that tasteless smoke treated samples were consistently more tender and juicy, both raw and cooked, than the untreated samples in both two and six month tests. In addition, there was no apparent difference in raw and cooked texture between the raw smoke and tasteless smoke treated samples further demonstrating that tasteless smoke and conventional smoke have comparable effects on texture.

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13/ Appendix 6 contains the test results.

## 2. Tasteless Smoke Preserves Aroma

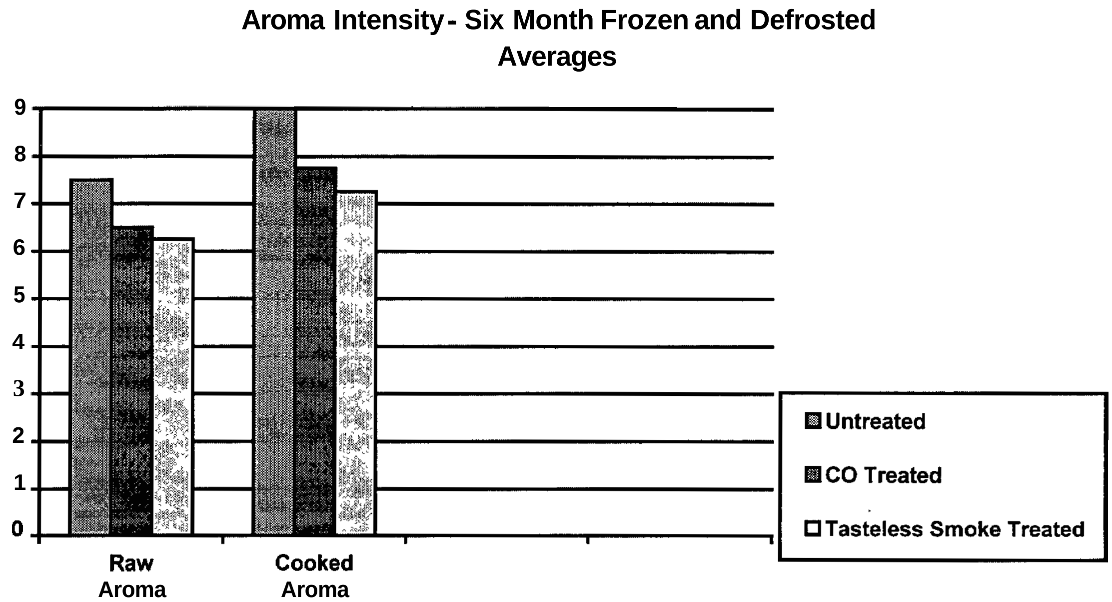
Dr. Maga measured aroma intensity and did not attempt to distinguish between off-odor (fishy) or desirable aromas. He utilized a trained ten-member sensory panel of six females and four males in an age range of **19** to 58. This group scored raw and cooked (broiled) samples on a 10-point aroma intensity scale with one being bland and 10 being strong. 14/ The following table and chart summarize these results (lower numbers are considered more desirable):

| Aroma Results for Raw and Cooked Tuna | | | | |
|---|---|---|---|---|
| | **Frozen for 2 Months** | | **Frozen for Six Months** | |
| | **Raw** | **Cooked** | **Raw** | **Cooked** |
| Untreated | 6.00 | 6.88 | 7.50 | 9.00 |
| Tasteless Smoke Treated | 5.25<br>5.33 | 6.13<br>6.33 | 6.25 | 7.25 |
| Conventional Smoke | 5.33 | 6.33 | N.A. | N.A. |
| Carbon Monoxide | 5.00 | 6.00 | 6.50 | 7.75 |
| **N.A. =** Not **Analyzed** | | | | |

These results show that the aroma of the untreated samples were consistently stronger both raw and cooked than the aroma of samples treated with carbon monoxide and tasteless smoke in both two and six month tests. Furthermore, there was little difference between raw smoke and tasteless smoke treated samples. In all cases cooked samples had a stronger aroma intensity than raw samples.

Interestingly, as illustrated by the chart below, the aroma of six month samples treated with carbon monoxide was considerably stronger both ,raw and cooked than the aroma **of** six month samples treated with tasteless smoke.

14/ *See* Appendix 7 for the test results.




This is a shift from the two month samples in which the carbon monoxide treated samples had a lower aroma, although to a much lesser degree. These data indicate a unique property of tasteless smoke in better preserving aroma during longer term frozen storage. Tasteless smoke treatment, therefore, influences tuna aroma differently than either carbon monoxide treatment or no treatment and has a preservative effect by preventing the development of strong fish odors during freezing. It is postulated that these preservative effects are due in part by preventing the oxidation of the iron ion in the myoglobin. 15/

## C. Antimicrobial and Antioxidative Properties of Tasteless Smoke

Tasteless smoke also offers anti-microbial and antioxidative properties. Preservation results both from a reduction of microbial counts during smoking and an extension of the shelf life of the treated fish. Conventional smoke contains numerous compounds with antioxidant-properties such as pyrocatechol, hydroquinone, guaiacol, eugenol, isoeugenol vanillin, salicylaldehyde, 2-hydroxybenzoic acid, and 4-hydroxybenzoic. 16/ These antioxidative phenolic derivatives will retard lipid-associated rancidity in seafood.

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15/ *See also* Judge, Aberle, Forrest, Hedrick and Merkel, "Principles of Meat Science" (undesirable odors can be prevented **by** immobilizing the iron atom in myoglobin).

16/ Toth, "***Smoke-related phenolic compounds with proven antioxidative properties,***" Advanced Food Rest., 29, 87, (1984).

According to Dr. Maga, "any phenolic that can produce a quinid structure will demonstrate some degree of [antioxidative] functionality." 17/ Tasteless smoke contains aromatic phenols, albeit at concentrations below the taste and odor threshold, and they will demonstrate antioxidative functionality.

Tasteless smoke also has a preservative effect by lowering the pH of the fish. The carbon monoxide and carbon dioxide in the tasteless smoke react with the water naturally present in the seafood to form carbonic acid. Even small pH changes can be significant and result in an increase in shelf life. A study analyzed the effect of tasteless smoke on the pH of seafood and the results are summarized in the table below. 18/

| **pH of Seafood Frozen for Two Months** | |
|---|---|
| Untreated | 5.97 |
| Tasteless Smoke Treated | 5.95 |
| Conventional Smoke Treated | 6.10 |
| Tasteless Smoke Treated | 6.06 |

These data show that, in all cases among species, each tasteless smoke treated sample was more acidic than either an untreated sample or a conventionally smoked sample cut from the same fish.

## D. Tasteless Smokes Fixes Color

Tasteless smoke also has a preservative effect in that it maintains the color of the seafood during frozen storage. Tasteless smoke "fixes" the color of tuna and other red-meat seafood in the same way that nitrates and nitrites fix the color of cured meats (*i.e.,* by reacting with the myoglobin to form compounds other than oxymyoglobin).

Just as the resulting color of pork treated with nitrates differs slightly from the uncured color, the color of red-meat seafood treated with tasteless smoke

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17/ Maga, ***"Smoke in** Food **Processing,"*** Chapter 7.

18/ ***See*** Appendix ***8,*** "pH Measurements Tests."

differs slightly from the untreated color. 19/ The difference in color is primarily attributable to an increase in the yellowness of the sample, although there are also subtle differences in the redness and lightness. The slight yellowing of treated seafood parallels a slight increase in the yellow component of untreated seafood that occurs naturally during the freezing and thawing process.

An independent laboratory measured the effect of tasteless smoke on the color of tuna and other red-meat seafood. Using a Hunter Lab Color Difference Meter, the laboratory measured the lightness, yellowness and redness of 147 samples of untreated, tasteless smoke treated, and carbon monoxide treated fish that had been frozen and stored for either six or two months. The laboratory measured the color of the samples after they had been thawed in a refrigerator for **24** hours. The same samples were then placed in household resealable bags and held at 4°C for five days and the color measurements were repeated.

The samples were taken from yellowfin, bigeye, and albacore tuna, and salmon of varying sizes and grades typically used to produce products for the U.S. market. The color properties of five fresh chilled tuna (three yellowfin and two bigeye) of varying weights and grades were also tested to demonstrate the impact of tasteless smoke on the color of the product. 20/ The results from the analysis are summarized below:

### 1. Lightness

Lightness values, which measure the intensity of the color, were lower for tasteless smoke treated frozen and defrosted tuna samples than for either carbon monoxide or untreated frozen and defrosted samples. The tasteless smoke treated samples had the lowest color "intensity"ratings of the previously frozen samples tested.

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191 *See* Appendix 9, "Untouched Color Photographs," which shows the color of treated and untreated samples.

201 See Appendix **5,** "Data of Color Properties Test Results," for the color test results.

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| Product | Lightness | |
|---|---|---|
| | **Day 1** | **Day 5** |
| Fresh Tuna | 80.26 | **N.A.** |
| Untreated Tuna (Frozen 2 Mths) | 80.55 | 81.10 |
| Tasteless Smoke Treated (Frozen 2 Mths) | 80.49 | 80.72 |
| CO Treated (Frozen 2 Mths) | 80.74 | *80.88* |

**2.** Yellowness

**A** natural "yellowing" occurs in frozen and defrosted.untreatedtuna and other species as evidenced by a **58** percent increase in yellowness values. The treatment with tasteless smoke does not prevent this "yellowing" as the yellowness value of the tuna steak continues to increase for the tasteless smoke treated product during storage at frozen temperatures. The frozen and thawed tasteless smoke treated sample is slightly more yellow in color than the untreated frozen and thawed sample and significantly more yellow than the untreated fresh sample.

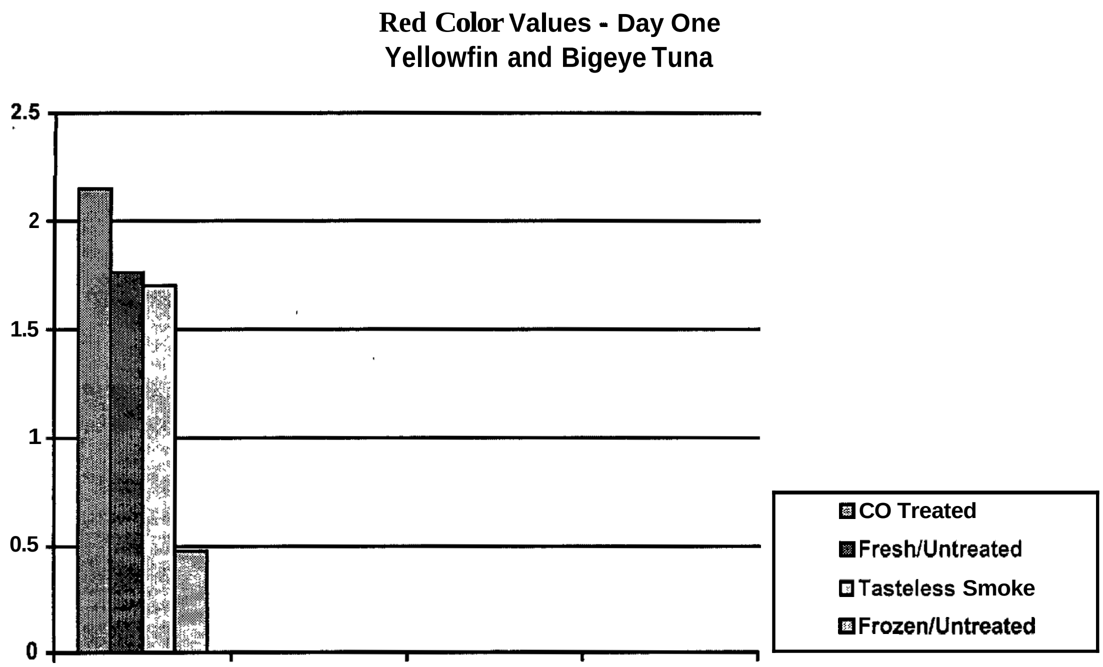
| Product | Yellowness | |
|---|---|---|
| | **Day 1** | **Day 5** |
| Fresh Tuna | +0.50 | **N.A.** |
| Untreated Tuna (Frozen 2 Mths) | +0.79 | +0.38 |
| Tasteless Smoke Treated (Frozen 2 Mths) | +0.85 | +0.50 |
| CO Treated (Frozen 2 Mths) | +0.95 | +0.83 |

**3.** Redness

The redness of tuna is an important characteristic because a darker, redder color is considered more desirable by consumers. The following tables summarize test results for carbon monoxide treated, tasteless smoke treated and untreated yellowfin and bigeye tuna steaks that had been frozen for two months. These frozen samples were thawed and their red color was compared to that of fresh tuna steaks.

| Comparison of Average Redness Values for Frozen and Thawed Tuna (1 and 5 Days) with Fresh Tuna | | |
|---|---|---|
| **Product** | **Redness** | |
| | **Day 1** | **Day 5** |
| Fresh Tuna | **1.76** | **N.A.** |
| Untreated Tuna (Frozen **2** Mths) | **0.48** | **0.31** |
| Tasteless Smoke Treated (Frozen 2 Mths) | **1.70** | **1.47** |
| CO Treated (Frozen **2** Mths) | **2.15** | *2.00* |

After two months of frozen storage and **24** hours of thawing, tasteless smoke treated tuna has an average redness measurement of **1.70** which is approximately the same as the **1.76** average measurement for the fresh untreated tuna fillet. (The average redness is also **1.70** for tasteless smoke treated tuna that have been frozen for six months and thawed.) The carbon monoxide treated tuna average score of **2.15** shows that carbon monoxide, unlike tasteless smoke, substantially increases (*i.e.* by **24** percent) the redness of tuna steaks. The untreated sample had the lowest redness ratings which demonstrates the adverse impact that two months of freezing has on the redness of tuna. These results are summarized in the chart below:




The redness of the tasteless smoke treated product, however, declines once the product is thawed. The average redness measurement for tasteless smoke treated tuna declines **14%** over five days of refrigeration while the average measurement for carbon monoxide treated tuna declines 7% over the same period. This carbon monoxide treated tuna still remains in an enhanced state **14%** redder on its fifth day than fresh tuna on its first day. While individual sample measurements will vary with species and grade, the overall average of a large sample size will consistently show carbon monoxide treated tuna at an enhanced level of redness and tasteless smoke treated tuna at a comparable level of redness to fresh tuna.

Dr. Maga concludes in his report on color measurement that:

> all carbon monoxide treated samples were redder in color than untreated and tasteless smoke treated samples, with the untreated samples the darkest in color. With storage, the carbon monoxide treated samples held more red color, the untreated samples lost the most color, and the tasteless smoke treated samples were in between.

He adds that there were "some differences among fish types, no differences between fish loins or fish fillets..." The data also showed that higher grades of fish displayed higher color values.

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These test results show that treatment with tasteless smoke as applied "fixes" the red color characteristic at its fresh level until thawing at which point a natural fading occurs during refrigerated storage. Treatment with carbon monoxide "enhances" the red color characteristic of equivalent samples throughout the freezing, thawing, and storing process until used with less degradation of this enhanced color.

Tasteless smoke also has the same general effect on salmon. These data show that without tasteless smoke treatment the color degrades in the frozen state and continues to fade more rapidly after thawing than tasteless smoke treated samples. Thus, using the same ingredient and means of treatment for salmon as tuna produces the same results of color "fixing" and preservation.

**Redness Results for Salmon (Compared to Fresh/Unfrozen)**

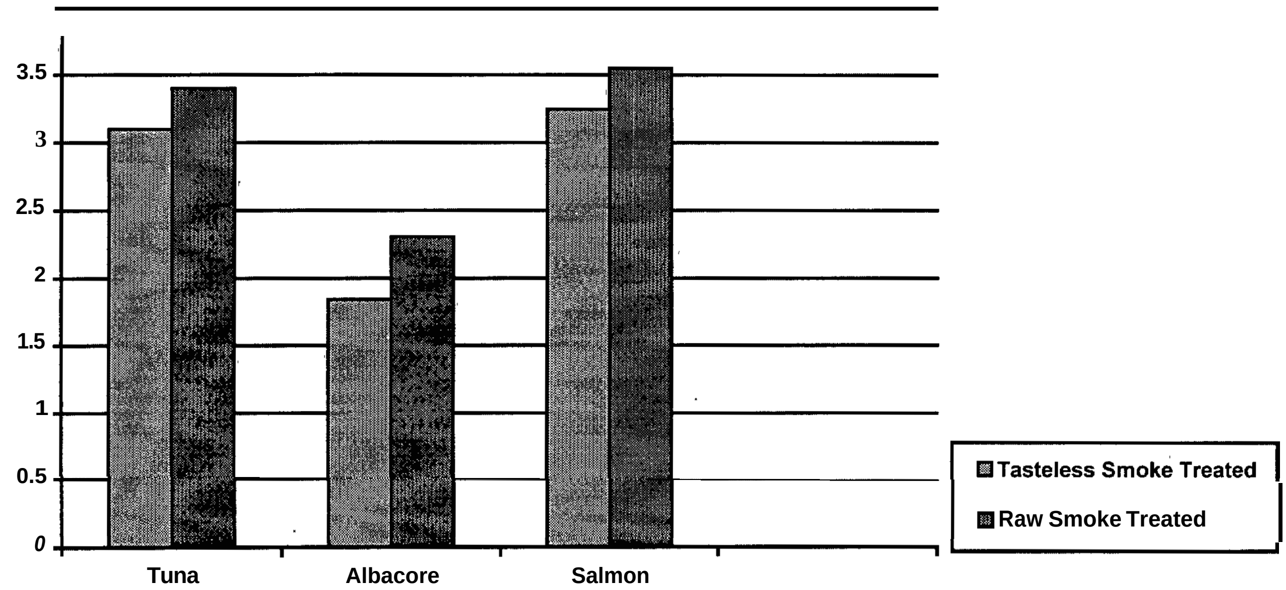
| | **Thawed 1 Day** | | | **Thawed 5 Days** | | |
|---|---|---|---|---|---|---|
| | **High** | **Low** | **Avg** | **High** | **Low** | **Avg** |
| Untreated | 3.20 | **3.10** | **3.15** | 2.80 | 2.70 | 2.75 |
| Tasteless Smoke Treated | 4.00 | **3.50** | **3.75** | 3.80 | **3.30** | **3.55** |
| Carbon Monoxide Treated | 4.40 | **4.30** | **4.35** | 4.20 | 4.20 | **4.20** |

### E. Tasteless Smoke Has the Same General Effect on Color as Conventional Smoke

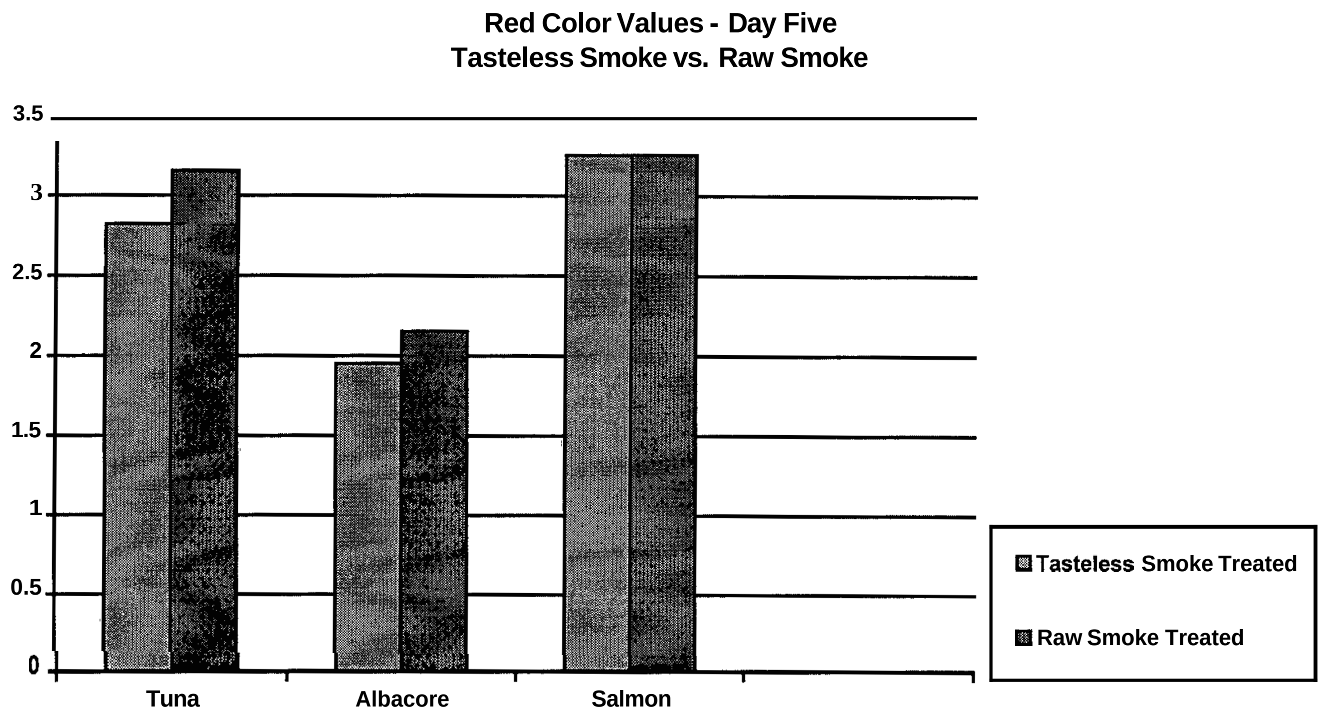
Tasteless smoke has the same general effect on the color of seafood as conventional smoke. Dr. Maga used the Hunter Lab Color Difference Meter to test the hypothesis that raw smoke and tasteless smoke behave similarly as ingredients in the treatment of seafood. These results, as illustrated in the chart below, consistently showed the raw smoke treated samples to be redder than the super-purified tasteless smoke treated samples for all species. 21/

21/ *See* Appendix 10, for the test results.

Red Color Values - Day One
Raw Smoke vs. Tasteless Smoke




The results further showed a natural fading of red color over the five day storage period for both raw smoke and tasteless smoke treated samples as illustrated in the chart below.




These tests used a higher grade of tuna, Japan "A' grade, than the other tests which used a Japan "B" grade or "#1" cooking grade. The higher grades of tuna have more vital myoglobin cells which would more easily discern any differences between raw smoke and tasteless smoke. The comparison of raw smoke with super-purified tasteless smoke treated samples shows that super-purification does not increase color imparting attributes from raw smoke levels. On the contrary, "super" filtering reduces somewhat the color imparting attributes of the resultant tasteless smoke from raw smoke levels.

## F. Tasteless Smoke is Different than Carbon Monoxide

During the summer of 1997, the Office of Seafood at FDA released a letter to the seafood industry in which the agency took the position that carbon monoxide could not be used in the treatment of raw tuna because it is an unapproved food additive and because it economically adulterates the product. Since issuing that letter, Hawaii International Seafood has met with individuals in the Office of Seafood to clarify the distinctions between tasteless smoke and carbon monoxide. As part of that meeting, FDA asked for data demonstrating that carbon monoxide and tasteless smoke have a different functional effect when added to food. The following studies, in addition to the color studies discussed previously, establish that this is the case.

### 1. Tasteless Smoke Has a Different Effect on the Color of Tuna than Carbon Monoxide

Samples of yellowfin and albacore tuna were treated with tasteless smoke, treated with carbon monoxide, and frozen and thawed. An independent laboratory convened a focus group which was asked to rate the quality of various characteristics 24 hours after thawing and 72 hours after thawing. 22/

The focus group reported that 24 hours after thawing, the carbon monoxide treated yellowfin was rated "bright unnatural red" while the tasteless smoke treated yellowfin was "natural red" and not as bright as carbon monoxide treated. After 72 hours, the carbon monoxide treated yellowfin was "slightly faded, but still bright unnatural red," while the tasteless smoke treated yellowfin was "slightly faded no longer a sashimi red."

There is little change in color of yellowfin tuna treated with tasteless smoke compared with its fresh untreated state, while there is a substantial bright unnatural red-pink color of the same tuna treated with carbon monoxide. Further, the tasteless smoke treated yellowfin and albacore tuna fade naturally with time after thawing while the carbon monoxide treated samples retain substantially all of the bright unnatural color.

### 2. Tasteless Smoke Treated Tuna Has a Different Taste Than Carbon Monoxide Treated Tuna

Raw and cooked tasteless smoke treated yellowfin and albacore tasted similar to fresh after thawing. Raw carbon monoxide treated yellowfin and albacore exhibited a flat "plastic" taste, while cooked carbon monoxide treated product did not have much flavor. Those in the focus group panel by far preferred the cooked tasteless smoke treated yellowfin as the best of all the samples exhibiting a rich, full fresh-like taste.

### 3. Tasteless Smoke Treated Tuna has a Different Texture Than Carbon Monoxide Treated Tuna

The focus group panel was asked to rate the firmness, or resiliency, of the samples. Here the untreated sample displayed significant softness and moisture loss after thawing. By comparison, the carbon monoxide treated samples were very firm with little moisture loss and the tasteless smoke treated samples were slightly softer with more moisture loss. After three days the carbon monoxide treated samples were still firm while the untreated and tasteless smoke treated samples were softer. The tasteless smoke treated tuna retained more of the

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22/ *See* Appendix 11, for the test results.

firmness of fresh tuna than the untreated tuna, yet degraded naturally after thawing.

### 4. Tasteless Smoke Treated Tuna Has Less Residual Carbon Monoxide in the Flesh Than Carbon Monoxide Treated Tuna

As discussed earlier, seafood treated with raw smoke or tasteless smoke has myoglobin molecules with open receptors that undergo a chemical reaction with a variety of compounds present in the smoke--carbon monoxide, nitrous oxide, nitrous dioxide--that stabilizes the myoglobin iron and keep it from oxidizing. Different species, and different grades of different species, have different amounts of vital myoglobin cells available for such reactions. This can be viewed as the capacity, or potential for color reaction. Species and grades with a higher capacity will have proportionately higher saturations. This is readily apparent in the grading of fresh tuna. The greater the number of myoglobin molecules, the greater the capacity for oxygen color reaction as oxymyoglobin.. The more the saturation of oxymyoglobin, the redder the fresh meat.

Treatment with either chemical carbon monoxide gas or tasteless smoke will result in a saturation of a portion of the capacity for color reaction of the myoglobin molecules into carboxymyoglobin. It is not possible to establish a maximum level of residual carbon monoxide per kilogram of fish since carbon monoxide saturation will be higher for higher grades and for certain species given identical treatment procedures. However, it is possible to compare residual carbon monoxide levels' of chemical carbon monoxide treated versus tasteless smoke treated identical samples. 23/

Residual Carbon Monoxide Levels
**(micrograms per kilogram)**

| | Lab 1 | | | Lab 2 | | |
|---|---|---|---|---|---|---|
| | High | Low | Avg | High | Low | Avg |
| Untreated | 49 | 30 | 39 | 56 | 8 | 29 |
| Tasteless Smoke Treated | 1400 | 400 | 768 | 416 | 101 | 243 |
| Carbon Monoxide Treated | 2100 | 240 | 1142 | 682 | 76 | 371 |

23/ *See* Appendix 12, "Residual CO Level Test Results," for the data.

On an absolute level the measurements by the laboratory number 1 are 2.5 times higher than the measurements of laboratory number 2. These differences may be attributable to equipment, testing procedures, and/or the capacity of the varying grades and species. More importantly, on a comparative level, both laboratories showed that carbon monoxide treated tuna showed about 50 percent higher average residual carbon monoxide levels than tasteless smoke treated tuna.

### *G.* Other Benefits of Tasteless Smoke Treated Tuna

#### 1. The Use of Tasteless Smoke Enables the Food Industry to Comply with Public Health Recommendations

There is an increasing concern among FDA and other public health authorities regarding the safety of consuming raw, unprocessed seafood because of possible parasite infestation. The 1997 Food Code requires raw, marinated, or partially cooked fish to be frozen to ensure destruction of parasites. The Food Code specifies that the fish should be frozen throughout at a temperature of -20°C for seven days or - 35°C for 15 hours in a blast freezer. The Food Code is a model code published by FDA that is intended to serve as the framework for local and state ordinances regarding the handling of food in restaurants and retail stores. Although the Food Code is not a federal law, some state and local jurisdictions incorporate all of its provisions into their statutes and ordinances.

Implementing the Japanese method of super cold freezing (-76°F or less) (-60°C or less) and storage to preserve color and kill parasites is impractical in the U.S. because of the retrofitting and capital investment required. It would cost millions of dollars to add super cold freezers to every cold storage facility, seafood distributor facility, restaurant, sushi bar, and supermarket across the U.S. Because of this high cost relative to the size of the U.S. market, super freezers are not a practical solution.

It is our understanding that many sushi establishments and other restaurants that serve raw fish dishes are reluctant to comply with the 1997 Food Code recommendation because frozen fish frequently lacks the taste, texture and appearance of fresh fish. The tasteless smoke treated product, however results in a product that is comparable in taste, texture, appearance and overall palatability to the non-frozen tuna. The use of tasteless smoke, therefore will prove valuable in helping restaurants comply with the 1997 Food Code and with the recommendations of FDA and other public health officials regarding the freezing of seafood that is to be consumed raw.

### 2. Tasteless Smoke Has Economic Advantages

The consumer is also receiving an economic benefit because frozen tuna steaks are much less expensive than fresh steaks primarily due to the cost differences between air freight and ocean freight. Fresh fish is typically air freighted from Pacific fisheries to the U.S. on ice in H & G form (whole with the head and gills removed). The average cost of such air freight is $1.92/lb. Generally, 53% of this fish will be lost during filleting so the per pound air freight, where calculated on the basis of the edible tuna, increase to $4.09/lb. In contrast, the tasteless smoke treated products are cut into steaks or fillets near the Pacific fisheries and treated with the tasteless smoke and frozen. The frozen fillets and steaks are shipped via ocean liners to the U.S. at a cost of about $0.19/lb. Although the tasteless smoke technology will add some costs to the raw tuna, the savings in air freight far exceeds these costs, so the economic savings could be passed onto the consumer in the form of lower seafood prices.

For example, fresh Indonesian tuna is delivered to master distributors in the U.S. at an average price of $3.35/lb. It will cost each U.S. distributor approximately $.17/lb. of H & G tuna to fillet into steaks. After filleting loss of *53%* of the unused fish, the yielded fresh steak cost is $7.50/lb. Hawaii International Seafood, Inc. will deliver the exact 'same grade of frozen tuna steak, treated with tasteless smoke, for $4.95/lb. to the master distributor. This is a savings to the consumer of $2.55/lb. at the master distributor level.

In addition, the retailer has the added benefit of being able to stock frozen inventory and thaw out only what is needed on demand, thus avoiding the degeneration of quality associated'with aging fresh seafood. This allows the retailer to maintain a consistent, high quality, "previously frozen" tuna steak supply available for his customers while reducing losses to spoilage.

## IV. METHODS FOR DETECTING THE SUBSTANCE IN FOOD

There is not a method for detecting the presence of the ingredient tasteless smoke in food. There are methods, however, which can be used to detect for the presence of the components of tasteless smoke, such as the nitrogen, oxygen, carbon monoxide, carbon dioxide, aromatic phenols and hydrocarbons. These methods are as follows:

| Component: | Method Number | Abbreviated Method Name |
|---|---|---|
| Carbon Dioxide | ASTM D1946 | Analysis of Reformed Gas by Gas Chromatography (GC) with Thermal Conductivity Detection (TCD) |

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| | | |
|---|---|---|
| **Carbon Monoxide** | ASTM **D1946** | Analysis of Reformed Gas by Gas Chromatography (GC) with Thermal Conductivity Detection (TCD) |
| **Aromatic Phenols (gaseous vapor)** | EPA TO-8 | Phenols and Cresols in Ambient Air by High Pressure Liquid Chromatography HPLC |
| **Hydrocarbons** ($C_5$ to $C_{10}$) | EPA **TO-14** | Volatile Organic Compounds in Ambient Air by GC/FID (flame ionization detection) |
| **Hydrocarbons** ($C_2$ to $C_4$) | EPA **TO-14** | Volatile Organic Compounds in Ambient Air by GC/FID |

## V. CLAIM OF CATEGORICAL EXCLUSION FROM THE ENVIRONMENT ASSESSMENT

Hawaii International Seafood claims a categorical exclusion from the environmental assessment (EA) and environmental impact statements (EIS). Under the recently finalized environmental impact consideration regulations, actions involving "the approval of food additive, color additive, or GRAS petitions for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in the food," ordinarily do not require the preparation of an EA or EIS. 24/

FDA clarified in the preamble to the proposed rule that "[e]xamples of the types of additives and GRAS substances that belong to this class are the color additives added to foods listed in **21** CFR parts **73** and **74,** most of the direct food additives listed in part **172 (21** CFR parts **172)**, and certain GRAS substances listed in part **184 (21** CFR part **184.).**25/ FDA further offered that "examples of substances not included in this class for which this categorical exclusion is being proposed are the substances intended to replace macronutrients in food (such as sweetening agents intended to replace sugar *e.g.,* see §§ **172.800** and **172.804,** and fat substitutes *e.g.,* **184.1498."**26/

24/ **62** ***Fed. Reg.*** **40570, 40595 (1997)** (to be codified at **21** CFR § 25.32(k) **(1998)).**

25/ **61** ***Fed. Reg.*** **19476, 19482 (1996)** ***(emphasis added).***

26/ *Id.*

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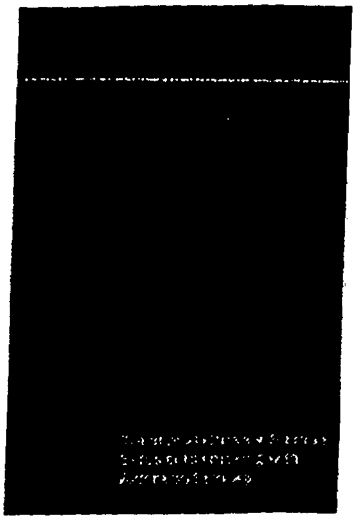
Although the GRAS premarket notification proposed rule would not require an environmental assessment, the GRAS affirmation petition regulations do require one. Because the agency has not yet issued the final rule that would establish the GRAS premarket notification procedures, Hawaii International Seafood submits a request for a categorical exclusion.

This GRAS premarket notification complies with the categorical exclusion criteria in 21 CFR § 25.32(k) (1998). Tasteless smoke is a direct food ingredient that is intended to remain in the food through ingestion, and it is not a macronutrient. In addition, to the knowledge of Hawaii International Seafood, there are no extraordinary circumstances that would refute this categorical exclusion.

# Appendix 1

## Testimonials Establishing Pre-1958 Use of Filtered Cold Smoke to Preserve Seafood



## Cold Smoked Chinook Salmon

Slowly smoked with natural smoke from alderwood is the key to the rich flavor of Grandpa Anton's Traditional Smoked Salmon. Salmon fillets are *cured* and then bung in our two old-fashioned gravity smokehouses. After a short drying time *the* slow cold smoking proce begins. The flavorful alderwood smoke continuously generated in the smokehouse drifts up past the salmon sides and out the smoke-stack. The resulting smoked salmon has a delecta smokey flavor and firm texture that is sure to please your family and friends.

Scandinavian-style Smoked Salmon open-faced sandwiches served on a dark rye, preferabl Swedish or molasses rye, spread with cream cheese are a traditional Scandinavian delicacy family gatherings, weddings and other festive occasions Lhese finger sandwiches are alway and are often the first item to disappear from the buffet. The buttery rich flavor and cold s texture of our lightly cured Smoked Salmon Lox is delicious on bagels with cream cheese. fillets are smoked on racks in our two modem horizontal air-flow smokehouses until (hey r savory perfection.

Traditional Style Cold Smoked Chinook Salmon Lox Style Cold Smoked Salmon Side Lox on Gold

Show Order Josephson's Smokehouse & Specialty Seafood Info Request Catalog

## Lox Style Cold Smoked Salmon Side

**lox lox lox lox lox cold smoked salmon cold smoked salmon cold smoked s cold smoked salmon cold smoked salmon**

Josephson's most delicate process. Highest quality farm-raised salm lightly salted and smoothly smoked with alderwood to produce a won flavor and naturally buttery textured lox. If breakfast at home on Sunday is incomplete without lox and bagels or 1 scrambled eggs, then our individually vacuum packed Chinook Lox sides will enable you to keep a supply on-han satisfy your craving. Simply freeze upon arrival and use as needed. Vacuum-sealed sliced lox packages keep 3 t weeks under refrigeration. Once opened use within 7 days.

Quantities below are in pounds. For example, a 3 lb side sells for $88, a 4 lb side sells for $117. You may also ch have your Lox sliced by us, but please remember that this will add $3 per pound to your order when processed.

Must be shipped by 2nd Day Air or Next Day Air.

4801S Three Pounds: *$88.00*, 4/$117.00, 5/$145.00 Order

Show Order Josephson's Smokehouse & Specialty Seafood Info Request Catalog

## Traditional Style Cold Smoked Chinook Salmon

traditional cold smoked chinook salmon traditional cold smoked chinook s traditional cold smoked chinook salmon traditional cold smoked chinook s traditional cold smoked chinook salmon

Josephson's famous 77 year-old family Scandinavian process. High quality Pacific Chinook Salmon are dry salted and slowly smoked wit alderwood to produce a rich smoky flavor and firm texture similar to Since 1920 Grandpa Anton's Traditional Smoked Salmon has found regulars over the years. For them this has been the "perfect present" gift that is right for the friend who has everything, the relative who is please, or the business associate you want to impress. More so toda ever before, food has become the universally appealing gift - one that can be repeated annually without misgivin after year our customers have enjoyed giving and receiving our Traditional Smoked Salmon.

Refrigerate 6 weeks/freeze 6 months. Quantities below are in pounds. For example, 1 lb sells for $29, 2 lbs sell fo You may also choose to have your Traditional sliced by us, but please remember that this will add $3 per pound t order when processed.

Must be shipped by 2nd Day Air or Next Day Air.

21510S One pound = $29.00, 2/$57.00, 3/$84.00, 5/$129.00 Slicing: Unsliced Ord

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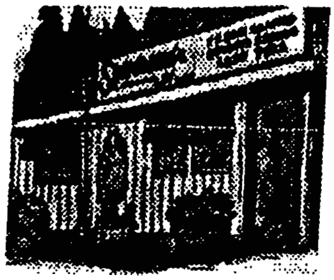

# SPORTSMEN'S CANNERY & SMOKEHOUSE

***Naturally Northwest***

That's the best way we can describe the natural, pure product in our Seafood, We include no preservatives, water, **or** oil in **the** gourmet canned **fish** we offer. The clean, clear Pacific waters provide **us** at **Sportsmen's Cannery** & **Smokehouse with** only **the** freshest top-quality fish **for** our cans. **You,** as the customer, are getting the best that money can **buy.**

**The Sportsmen's Cannery** & **Smokehouse** was established in **1955** and has been run continuously **as** a **family** business. **We** have stayed in business because **of** the quality of our **products** and the enthusiasm of our customers. We **can** for sport fishermen and for our **customers. All of our seafood products** are **troll** caught, hand-packed and canned **fresh from** the ocean. **Our** smoked seafood **is** specially brinned and alder smoked **without** chemical additives **or** coloring. Besides **being** delicious and ready ***to*** eat right out ***of*** the can, seafood **is** low **in** calories and **high** in vitamins and protein as well as being a natural source **of calcium** and **0-MEGA 3** (essential **fatty** acids).

**Click Here to *See* Our** Selection **of** THE Finest Canned **Seafoods In** The World !

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SINCE 1921
Lascco

December 18, 1997

Jeanne W. Evans
HAWAII INTERNATIONAL SEAFOOD, INC.
P.O. Box 30486
Honolulu. HI 96820

TO WHOM IT MAY CONCERN:

This letter is to verify that LOS ANGELES SMOKING & CURING COMPANY (LASCCO) has been processing smoked and pickled fish since 1921.

LASCCO processes and markets a complete line of products nationally and is the largest processor in the western United States.

Should you require additional information, please feel free to contact me.

Sincerely,

Richard D. Schaffer
Vice President of Sales & Marketing

RS:lcp

000038

778 Kohler Street, Los Angeles, CA 90021
Sales & Marketing: Tel (213) 628.1246 Fax (213) 614.8857
Accounting & Administration: Tel (213) 622.0724 Fax (213) 624.2369

# Appendix 2

# Chemical Composition of Wood Smoke

United States
Environmental Protection
Agency

Office of Air Quality
Planning and Standards
Research Triangle Park, NC 27711

EPA-453/R-93-036
December 1993

Air

EPA

# A SUMMARY OF THE EMISSIONS CHARACTERIZATION AND NONCANCER RESPIRATORY EFFECTS OF WOOD SMOKE

Office of Air Quality Planning and Standards
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# A SUMMARY OF THE EMISSIONS CHARACTERIZATION AND NONCANCER RESPIRATORY EFFECTS OF WOOD SMOKE

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Office of Air Quality Planning and Standards
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Research Triangle Park, NC 27712

Environmental Criteria and Assessment Office
office of Health and Environmental Assessment
Office of Research and Development
Research Triangle Park, NC 27712

## EXHIBIT E
CHEMICAL COMPOSITION OF WOOD SMOKE

| Species 1 | g/kg wood 2 | Physical State 3 | Reference |
|---|---|---|---|
| Water Vapor | 35-105 | V | 2 |
| Carbon Dioxide | 70-200 | V | 2 |
| Carbon Monoxide | 80-370 | V | 4,5 |
| Methane | 14-25 | V | 5 |
| VOCS (C2-C&) | 7-27 | V | 5 |
| Aldehydes | 0.6-5.4 | V | 4,6 |
| Formaldehyde | 0.1-0.7 | V | 4,6 |
| Acrolein | 0.02-0I | V | 6 |
| Propionaldehyde | 0.1-0.3 | V | 4,6 |
| Butryaidehyde | 0.01-1.7 | V | 4,6 |
| Acetaldehyde | 0.03-0.6 | V | 4,6 |
| Furfural | 0.2-1.6 | V | 7,8 |
| Substituted Furans | 0.15-1.7 | V | 5 |
| Benzene | 0.6-4.0 | V | 9 |
| Alkyl Benzenes | 1-6 | V | 9 |
| Toluene | 0.15-1.0 | V | 7 |
| Acetic Acid | 1.8-2.4 | V | 7 |
| Formic Acid | 0.06-0.08 | V | 4,5 |
| Nitrogen Oxides (NO, N02) | 0.2-0.9 | V | 10 |
| Sulfur Dioxide | 0.16-0.24 | V | |
| Methyl chloride | 0.0-0.04 | V | 9 |
| Napthalene | 0.24-1.6 | V | 9 |
| Substituted Napthalenes | 0.3-2.1 | V/P | 9 |
| Oygenated Monoaromatics | 1-7 | V/P | 11 |
| Guaiacols | 0.4-1.6 | V/P | 11 |
| Phenols | 0.2-0.8 | VIP | 11 |
| Syringols | 0.7-2.7 | VIP | 11 |
| Catechols | 0.2-0.8 | V/P | 5 |
| **Total** Particulate Mass | 7-30 | P | 12 |
| Oxygenated PAHs | 0.15-1.0 | V/P | 13 |
| **PAHs** | | | |
| Fluorene | 0.00004-0.07 | V/P | 13 |
| Phenanthrene | 0,00002-0.034 | VIP | 13 |
| Anthracene | 0.00005-0.02 | V/P | 13 |
| Methylanthracenes | 0.00007-0.008 | V/P | 13 |
| Fluoranthene | 0.0007-0.042 | V/P | 13 |

| | | | |
|---|---|---|---|
| Pyrene | 0.0008-0.031 | V/P | 13 |
| Benzo(a) anthracene | 0.0004-0.002 | V/P | 13 |
| Chrysene | 0.0005-0.01 | V/P | 13 |
| Benzo-fluranthenes | 0.0006-0.005 | V/P | 13 |
| Benzo(e)pyrene | 0.0002-0.004 | V/P | 13 |
| Benzo(a)pyrene | 0.0003-0.005 | V/P | 13 |
| Perylene | 0.00005-0.003 | VIP | 13 |
| Ideno(1,2, 3-cd)pyrene | 0.0002-0.013 | V/P | 13 |
| Benz(ghi) perylene | 0.00005-0.011 | V/P | 13 |
| Coronene | 0.0008-0.003 | V/P | 13 |
| Dibenzo(a,h) pyrene | 0.0003-0.001 | V/P | 13 |
| Retene | 0.007-0.03 | V/P | 14 |
| Dibenz(a,h) anthracene | 0.00002-0.002 | V/P | 13 |
| Trace Elements | | | |
| Na | 0.003-0.018 | P | 15 |
| Mg | 0.0002-0.003 | P | 15 |
| Al | 0.0001-0.024 | P | 15 |
| Si | 0.0003-0.03 | P | 15 |
| S | 0.001-0.029 | P | 15 |
| Cl | 0.0007-0.21 | P | 15 |
| K | 0.003-0.086 | P | 15 |
| Ca | 0.0009-0.018 | P | 15 |
| Ti | 0.00004-0.003 | P | 15 |
| V | 0.00002-0.004 | P | 15 |
| Cr | 0.00002-0.003 | P | 15 |
| Mn | 0.00007-0.004 | P | 15 |
| Fe | 0.0003-0.005 | P | 15 |
| Ni | 0.000001-0.001 | P | 15 |
| Cu | 0.0002-0.0009 | P | 15 |
| Zn | 0.00007-0.004 | P | 15 |
| Br | 0.00007-0.0009 | P | 15 |
| Pb | 0.0001-0.003 | P | 15 |
| Particulate Elemental Carbon | 0.3-5 | P | 16 |
| Normal Alkanes (C24-C30) | 0.001-0.006 | P | 17 |
| Cyclic di- and triterpenoids | | | |
| Dehydroabietic | | | |

| | | | |
|---|---|---|---|
| acid | 0.001-0.006 | P | 18 |
| Isopimaric acid | 0.02-0.10 | P | 18 |
| Lupenone | 0.002-0.008 | P | 18 |
| Friedelin | 0.000004-0.00002 | P | 18 |
| Chlorinated dioxins | 0.00001-0.00004 | P | 19 |
| Particulate Acidity | 0.007-0.07 | P | 20 |

1. Some species are grouped into general classes as indicated by italics.
2. To estimate the weight percentage in the exhaust, divide the g/kg value by 80. This assumes that there are 7.3 kg combustion air per kg of wood. Carbon dioxide and water vapor average 12 and 7 weight percent respectively.
3. At ambient conditions: V= vapor, P = particulate, and V/P = vapor and/or particulate (i.e., semi-volatile).
4. DeAngelis (1980).
5. OMNI (1988)
6. Lipari (1984), values for fireplaces
7. Edye et al (1991), smoldering conditions; other substituted furans include 2-furanmenthanol, 2 acetylfuran, 5-methyl-2furaldehyde, and benzofuran.
8. Value estimated for pine from Edye et al (1991)from reported yield relative to guaiacol, from guaiacol values of Hawthorne (1989) and assuming particulate organic carbon is 50% of total particle mass.
9. Steiber et al (1992), values computed assuming a range of 3-20 g of total extractable, speciated mass per kg wood.
10. Khalil (1983)
11. Hawthome (1989), values for syringol or hardwood fuel; see also Hawthorne (1988)
12. Core (1989), DeAngelis (1980), Kalman and Larson (1987)
13. From one or more of the following studies: Cooke (1981), Truesdale (1984), Alfheim et al (1984), Zeedijk (1986), Core (1989), Kalman and Larson (1987); assuming a range of 7 to 30 grams particulate mass per kg wood when values were reported in grams per gram of particulate mass. Similar assumptions apply to references 14, 15, and references 17-19.
14. Core (1989), Kalman and Larson (1987)
15. Watson (1979), Core (1989, Kalman.and Larson (1987)
16. Rau (1989), Core (1989)
17. Core (1989)
18. Standley and Simoneit (1990); Dehydroabietic acid values for pine smoke, lupenone and isopimaric acid values for alder smoke, and friedelin values for oak soot.
19. Nestrick and Lamparski (1982), from particulate condensed on flue pipes; includes TCDDs, HCDDs, H7CDDs and OCDDs.
20. Burnet et al (1986); one gram of acid = one equivalent of acid needed to reach a pH of 5.6 in extract solution.

# Appendix 3

# Tasteless Smoke vs. Raw Smoke Seafood Analysis

**Tasteless Smoke vs. Raw Smoke Seafood Analysis**

November 20,1998

| | CO | $CO_2$ | C2-4 | C4-10 | Phenol | ID |
|---|---|---|---|---|---|---|
| Albacore | | | | | | |
| Tasteless Smoke A | 19 | 7925.7 | 18.3 | 605.0 | ND | 53 |
| Tasteless Smoke B | 24 | 2426.9 | 20.7 | 445.9 | | 55 |
| A and B Average | 22 | 5176.3 | 19.9 | 525.4 | | |
| A and B Composite | 17 | 4400.2 | ND | 3188.0 | | |
| Raw Smoke A | 23 | 5716.1 | ND | 429.4 | | 54 |
| Raw Smoke B | 52 | 904.8 | 9.6 | 1079.9 | | 56 |
| A and B Average | 38 | 3310.4 | 9.6 | 754.6 | | |
| A and B Composite | 47 | 3667.4 | 19.5 | 1955.0 | | |
| Salmon | | | | | | |
| Tasteless Smoke A | 15 | 12933.3 | 10.5 | 1165.2 | | 13 |
| Tasteless Smoke B | 119 | 5032.9 | 4.1 | 3580.9 | | SMK |
| A and B Average | 67 | 8983.1 | 7.3 | 2373.0 | | |
| A and B Composite | 17 | 4021.5 | 92.3 | 2481.5 | | |
| Raw Smoke A | 61 | 5023.1 | 63.4 | 240.0 | | 14 |
| Raw Smoke B | 13 | 16237.I | 229.3 | 1793.3 | | RS |
| A and B Average | 37 | 10630.1 | 146.3 | 1016.6 | | |
| A and B Composite | 26 | 2808.0 | 314.0 | 1736.3 | | |
| Yellowfin | | | | | | |
| Tasteless Smoke A | 16 | 760.3 | ND | 576.0 | | 42 |
| Tasteless Smoke B | 24 | 4599.2 | 13.9 | 499.1 | | 74 |
| A and B Average | 20 | 2679.5 | 13.9 | 537.5 | | |
| A and B Composite | 52 | 1593.6 | 272 | 4722.6 | | |
| Raw Smoke A | 24 | 1790.4 | 28.5 | 317.3 | | 41 |
| Raw Smoke B | 57 | 2076.5 | — | ( ) | | 73 |
| A and B Average | 41 | 1933.4 | — | — | | |
| A and B Composite | 51 | 2917.9 | 14.1 | 1710.4 | | |

ENVIRONMENTAL
ANALYTICAL SERVICE, INC

FAX
TRANSMISSION

1/19/99 1:44:56 PM

| | | | |
|---|---|---|---|
| Attention | Bill Kowalski | | |
| Company | Hawaii International Seafood | | |
| Location | Honolulu | CA | |
| FAX | 808-833-0712 | Phone | 808-839-5010 |
| Fax Sent By | Steve Hoyt | Total Pages | 2 |

MESSAGE

Bill,

I had to go back and review my Statistics a little but I thing I got it right. I ran a Studentt test to determine if there was a significant difference between tho averate tasteless smoke and the average raw smoke for the C4 to C10 hydrocarbons. The results of the test which are summarized in the attached table show that there is no significant difference. The test can be refined by taking into account the differences in the standard deviations of the two populations, but this should do the job.

Steve

# Tasteless Smoke VS. Raw Smoke Seafood Analysis

C4-C10 Hydrocarbon

| | | | |
|---|---|---|---|
| Tasteless Smoke | 605.0 | 1702.3 | 1203975.9 |
| Tasteless Smoke | 445.9 | 1702.3 | 1578436.3 |
| Tasteless Smoke | 252.4 | 1702.3 | 2102089.2 |
| Tasteless Smoke | 3188.0 | 1702.3 | 2207428.3 |
| Tasteless Smoke | 1165.2 | 1702.3 | 288431.7 |
| Tasteless Smoke | 3580.9 | 1702.3 | 3529294.5 |
| Tasteless Smoke | 2373.0 | 1702.3 | 449894.4 |
| Tasteless Smoke | 2481.5 | 1702.3 | 607217.6 |
| Tasteless Smoke | 576.0 | 1702.3 | 1268457.8 |
| Tasteless Smoke | 499.1 | 1702.3 | 1447580.0 |
| Tasteless Smoke | 537.5 | 1702.3 | 1356662.0 |
| Tasteless Smoke | 4722.6 | 1702.3 | 9122463.8 |
| Average | 1702.3 | | 25161941.3 |

| | | | |
|---|---|---|---|
| Raw Smoke | 429.4 | 1107.3 | 459521.3 |
| Raw smoke | 1079.9 | 1107.3 | 749.7 |
| Raw Smoke | 754.6 | 1107.3 | 124383.2 |
| Raw Smoke | 1995.0 | 1107.3 | 788046.8 |
| Raw Smoke | 240.0 | 1107.3 | 752174.6 |
| Raw Smoke | 1793.3 | 1107.3 | 470823.4 |
| Raw Smoke | 1016.6 | 1107.3 | 8222.9 |
| Raw Smoke | 1736.3 | 1107.3 | 395686.2 |
| Raw Smoke | 317.3 | 1107.3 | 624068.4 |
| Raw Smoke | 1710.4 | 1107.3 | 363753.7 |
| Average | | | 363753.7 |

1107.28

| | | | |
|---|---|---|---|
| Statistical Test | | s= | 1129.728 |
| Student t | | sx= | 483.7205 |
| | Experimental | t= | 1.230004 |
| | | n=20 | |
| Table | For 95% Confidence Limit | t= | 2.09 |

Interpretation: If the experimental t is greater then the Table value for t at a given confidence level then we would conclude there is a significant difference in the means of the two populations.

# Appendix 4

# Expert Testimonials that Tasteless Smoke is GRAS

Colorado State University

Department of Food Science
and Human Nutrition

Fort Collins, Colorado 80523-1571
(970) 491-6535
FAX: (970) 491-7252

January 15, 1998

Mr. William Kowalski
Hawaii International Seafoods, Inc.
P.O. Box 30486
Honolulu, Hawaii 96820

Dear Mr. Kowalski:

I was scheduled to be out of the country for two weeks, but I returned a few days early and found several pieces of correspondence from you. I hope you get this response in time to incorporate into your report.

Color measurement was performed using a Hunter lab color difference meter. The spelling you forwarded is correct.

Objective quantitative texture measurements were performed using an Allo-Kramer shear press (not sheet press). Uniform cores of flesh (1/2 inch in diameter) were placed on the cutting surface of the instrument and the samples were cut with the machine knife. The amount of force, in pounds per square inch, required to cut through the sample was automatically recorded. Three separate measurements were taken on each sample and the values obtained were averaged and reported to you.

GRAS opinion:

Based on my knowledge relative to smoke generation and use, and upon reading in detail your process for obtaining tasteless smoke, it is my professional opinion that your tasteless smoke product can/should be considered to be GRAS. It basically is a natural sub-fraction of liquid smoke which is currently a GRAS ingredient.

However, the GRAS approach and the use of CO may be in conflict under current regulations.

If you have any more last minute questions, you can call me during local time office hours (8-5) or please feel free to call me at home if I am not in the office ([redacted] (b) (6))

Sincerely,

Joseph A. Maga, Ph.D.

ENVIRONMENTAL
Analytical Service, Inc.

**FAX TRANSMISSION**

Anentic:: Bill Kowalski
Company Hawaii International Seafood
Location Honolulu CA
FAX 808-833-0712 Phone 808-839-5010
Fax Sent By Steve Hoyt Total Pages 1

MESSAQE

Dear Bill, 1/13/98

I would say that the tasteless smoke has less considerably lower concentrations of chemical compounds in it than the regular smoke sample. This would Including the amounts of particulates, volatile organics, phenols, and Carbon Monoxide. For this reason I would consider the tasteless smoke lo be generally recognized as a safe ingredient (GRAS).

Sincerely,
Steven D. Hoyt, Ph.D.

3421 Empresa, Suite A, San Luis Obispo, CA 93401 (805) 781-3585 Fax (805) 541-4550

ALKAR
932 DEVELOPMENT DRIVE • P.O. BOX 260 • LODI, WISCONSIN 53555 • 608/592-3211 • FAX: 608/592-4039

January 26, 1997

Mr. Bill Kowalski
Hawaii International Seafoods, Inc
PO Box 30486
Honolulu International Airport
Honolulu, Hawaii 96820
ph: 808-839-5010
fx: 808-833-0712

Dear Bill,

This letter is in response to your request for a review of your tasteless smoke product.

Vaporous smoke has been used for centuries as a means of preservation and quality enhancement for thousands of different food products including meat, fish, cheese, nuts, and others. In the past few decades, natural liquid smoke preparations derived from vaporous smoke have come into widespread use by the food industry. In the United States, the USDA and the FDA allow both vaporous and liquid smoke for external and internal use in the manufacture of smoked foods.

In my view, since your "tasteless smoke" is simply derived from purified vaporous smoke, it should also be allowed for use in food products. In the preparation of the tasteless smoke, the smoke from smoldering wood chips is filtered and separated to form the final tasteless smoke product. The smoke-generating equipment that is used to produce the smoke for your process is widely used throughout the food industry. Because nothing is added to the tasteless smoke, I believe it should be allowed for use in food products just as other vaporous and liquid smokes and their derivatives are allowed for use.

Best regards,

Robert E Hanson
Manager of Technical Development

B.S. Agricultural Engineering Technology — University of Minnesota
M.S. Meat Science — Iowa State University

# Appendix 5

## Data of Color Properties Test Results (Tuna and Salmon)

000053

**Color Properties - Day One**
**Fresh Tuna**

| Sample | Light | Red | Yellow |
|---|---|---|---|
| Bigeye - 81.2kg | | | |
| 179 | 80.7 | +2.1 | +0.7 |
| Yellowfin - 58.5kg | | | |
| 129 | 80.3 | +1.9 | +0.6 |
| Bigeye - 37.6kg | | | |
| 83 | 80.3 | +1.8 | +0.5 |
| Yellowfin - 36.2kg | | | |
| 92 | 79.9 | +1.1 | t0.2 |
| Yellowfin - 39.4kg | | | |
| 87 | 80.1 | +1.9 | +OS |
| Averages | 80.26 | +1.76 | +0.50 |

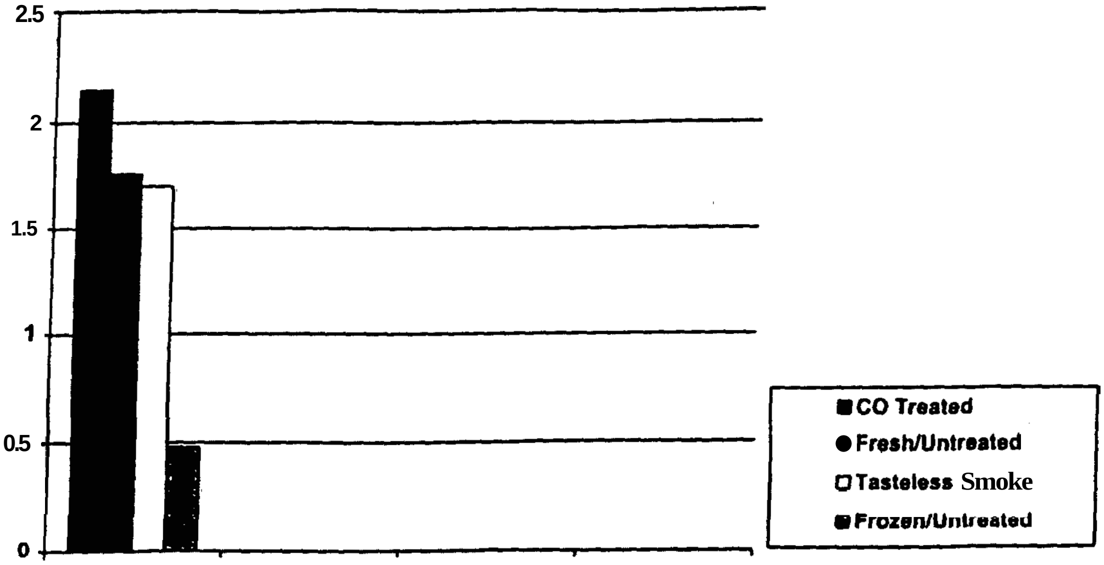
## Tuna Color Properties - Day One
## Two Month Frozen Defrosted

| | CO Treated | | | Untreated | | | Tasteless Smoke | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample | Light | Red | Yellow | Light | Red | Yelllow | Light | Red | Yellow |
| **Bigeye 46kg -Japan "B" Grade** | | | | | | | | | |
| 19 | 81.10 | +2.90 | +1.10 | 80.70 | +1.00 | +0.80 | 80.90 | +2.00 | +0.90 |
| 20 | 80.60 | +3.00 | +0.90 | 80.10 | +0.80 | +0.60 | 80.20 | +1 90 | +0.50 |
| 21 | 80.90 | +3.40 | +1.20 | 80.70 | +1.00 | +1.10 | 80.70 | +2.20 | +1.00 |
| 22 | 81.00 | +3.50 | +1.30 | 80.50 | +1.00 | +0.60 | 80.60 | +2.40 | +0.90 |
| 23 | 81.20 | +3 10 | +1.40 | 81.20 | +0.80 | +1.20 | 81.40 | +2 40 | +1.50 |
| 24 | 82.10 | +3.20 | +1.50 | 81.80 | +0.80 | +1.30 | 81.20 | +2.30 | +1.30 |
| Averages | 81.10 | +3.18 | +1.23 | 10.30 | +0.90 | +0.90 | 80.30 | +2.20 | +1.01 |
| **Yellowfin 38kg - #1 Cooking Grade** | | | | | | | | | |
| 39 | 80.80 | +2.30 | +1.10 | 81.10 | +0.60 | +1.20 | 81 00 | +1.90 | +1.20 |
| 40 | 81.00 | +2.10 | +1.20 | 80.80 | +1.00 | +1.20 | 80.70 | +1.80 | +1.10 |
| 41 | 81.60 | +2.30 | +1.20 | 80.80 | +0.80 | +1.30 | 80.80 | +1 60 | +1.20 |
| 42 | 80.90 | +2.00 | +1 10 | 80.40 | +0.50 | +0.60 | 80 10 | +1.20 | +0.70 |
| 50 | 80.30 | +1 90 | +0.70 | 80.20 | +0.50 | +0.80 | 80.20 | +1 00 | +0.60 |
| 51 | 8040 | +1 60 | +0.70 | 80.40 | +0.10 | +0 70 | 80.50 | +0 10 | +0.70 |
| 52 | 80.20 | +1.60 | +0.60 | 80.40 | +0.30 | +0 60 | 80.00 | +0.80 | +0.40 |
| 53 | 80.70 | +1.90 | +1.00 | 80.30 | +0.50 | +0.80 | 80.20 | +1.10 | +6.00 |
| Averages | 80.70 | +1.96 | +0.96 | 80.55 | +0.53 | +0.92 | 80.40 | +1.18 | +1.48 |
| **ellowfin 28kg - #1 Cooking Grade** | | | | | | | | | |
| 83 | 81.70 | +1.30 | +0.80 | 81.20 | +0.00 | +0.50 | 80.20 | +1.50 | +0.70 |
| 84 | 80.70 | +2.00 | +1.20 | 80.50 | +0.10 | +1.00 | 80.50 | +1.60 | +1.00 |
| 85 | 80.80 | +2.80 | +1.20 | 80.40 | +0.40 | +0.80 | 80.00 | +2.00 | +0.90 |
| 86 | 80.30 | +1.60 | +0.80 | 80.10 | +0.10 | +0.50 | 80.80 | +1.70 | +0.70 |
| 87 | 81.40 | +1.50 | +0.50 | 82.20 | +0.20 | +0.30 | 81.30 | +1.10 | +0.50 |
| verages | 80.90 | +1.84 | +0.90 | 80.80 | +0.16 | +0.62 | 80.60 | +1.58 | +0.76 |
| **Yellowfin 41kg - #1 Cooking Grade** | | | | | | | | | |
| 192 | 80.20 | +2 40 | +0.70 | 80.00 | +0.60 | +0.50 | 80.30 | +1.90 | +0.80 |
| 193 | 80.40 | +2.60 | +1.10 | 8040 | +0.60 | +0.80 | 80.20 | +2.20 | +0.90 |
| 194 | 80.10 | +2.20 | +0.60 | 80.20 | +0.90 | +0.80 | 80.50 | +2.50 | +0.90 |
| 195 | 80.20 | +1.60 | +0.90 | 80.10 | +0.20 | +0.80 | 80.00 | +1.60 | +0.90 |
| 205 | 80.20 | +2.40 | +0.60 | 80.00 | +0.60 | +0.40 | 80.50 | +2.30 | +0.70 |
| 206 | 80.40 | +2.30 | +1.00 | 80.30 | +0.30 | +0.90 | 80.70 | +2.10 | +1.30 |
| 207 | 80.10 | +1.90 | +0.70 | 79.60 | +0.00 | +0.30 | 80.00 | +1.80 | +0.70 |
| Averages | 80.20 | +2.20 | +0.80 | 80.10 | +0.45 | +0.64 | 80.30 | +2.05 | +0.88 |
| **Yellowfin U k g - #1 Cooking Grade** | | | | | | | | | |
| 217 | 80.80 | +1.90 | +0.80 | 80.50 | +0.60 | +0.80 | 80.60 | +1.60 | +0.60 |
| 218 | 81.00 | +1.90 | +1.10 | 81.00 | +0.50 | +1.00 | 81.00 | +1.90 | +1.30 |
| 219 | 80.80 | +1.60 | +0.80 | 80.80 | +0.30 | 9.90 | 80.50 | +1.60 | +0.60 |
| 220 | 81.30 | +1.90 | +1.10 | 81.00 | +0.30 | +1.00 | 80.30 | +1.30 | +0.90 |
| 221 | 80.60 | +1.60 | +0.80 | 80.00 | +0.00 | +0.40 | 80.00 | +1.50 | +0.50 |
| 227 | 80.70 | +1.10 | +0.70 | 80.70 | +0.60 | +0.90 | 80.70 | +2.10 | +1.00 |
| 230 | 80.60 | +1.80 | +1.00 | 80.00 | +0.00 | +0.60 | 80.30 | +1.00 | +0.70 |
| Averages | 80.82 | +1.68 | +0.90 | 80.67 | +0.32 | +0.80 | 80.49 | +1.57 | +0.80 |

## Tuna Color Properties - Day One
## Six Month Frozen and Defrosted

| | CO Treated | | | Untreated | | | Tasteless Smoke | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample # | Light | Red | Yellow | Light | Red | Yellow | Light | Red | Yellow |
| 8 | 82.80 | +1.50 | +0.50 | 82.70 | +1.70 | +0.40 | 82.20 | +0.90 | +0.60 |
| 9 | 83.40 | +1.80 | +0.40 | 83.50 | +1.90 | +0.30 | 83.00 | +1.10 | +0.50 |
| 10 | 83.60 | +2.40 | +0.70 | 83.10 | +1.00 | +0.50 | 83.40 | +2.40 | +0.70 |
| 12 | 83.20 | +2.40 | +0.60 | 87.90 | +0.90 | +0.40 | 83.10 | +2.40 | +0.60 |
| Averages | 83.26 | +2.03 | +0.56 | 84.30 | +1.38 | +0.74 | 82.93 | +1.70 | +0.60 |

Red Color Values • Day One
Yellowfin and Bigeye Tuna



# Tuna Color Properties - Day Five
## Two Month Frozen and Defrosted

| | CO Treated | | | Untreated | | | Tasteless Smoke | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample | Light | Red | Yellow | Light | Red | Yelllow | Light | Red | Yellow |
| **Bigeye 46kg - Japan "B" Grade** | | | | | | | | | |
| 19 | 81.40 | +2.70 | +1.00 | 81.30 | +0.70 | +0.50 | 81 10 | +1.80 | +0.70 |
| 20 | 80.80 | +2.80 | . +0.80 | 80.50 | +0.50 | +0.30 | 80 40 | +1.70 | +0.40 |
| 21 | 81.00 | +3.20 | +1.00 | 81.10 | +0.70 | +0.80 | 80.90 | +2.00 | +0.80 |
| 22 | 81.20 | +3.30 | +1.10 | 80.90 | +0.60 | +0.30 | 80.80 | +2.20 | +0.70 |
| 23 | 81.30 | +3 00 | +1.30 | 81.50 | +0.50 | +0.90 | 81.60 | +2 60 | +1.60 |
| 24 | 82.30 | +3.00 | +1.40 | 82.10 | +0.50 | +1.00 | 81.40 | +2.10 | +1 10 |
| Averages | 81.33 | +3.00 | +1.10 | 81.23 | +0.58 | +0.63 | 81.03 | +2.06 | +0.88 |
| **Yellowfin 38kg - #1 Cooking Grade** | | | | | | | | | |
| 39 | 81.00 | +2.20 | +1.10 | 81.50 | t0.30 | +0.90 | 81.20 | +1.70 | +1.00 |
| 40 | 81.10 | +2.00 | +1.00 | 81.30 | +0.50 | +0.90 | 80.90 | +1.60 | +0.90 |
| 41 | 81.70 | +2.20 | +1.10 | 81.30 | +0.50 | +1.00 | 81.00 | +1.40 | +1.00 |
| 42 | 81.10 | +1.90 | +1.00 | 80.80 | +0.20 | +0.50 | 80.30 | +1.00 | +0.50 |
| 50 | 80.40 | +1.70 | +0.60 | 80.60 | +0.20 | +0.50 | 80 40 | +0.80 | +0.40 |
| 51 | 80.50 | +1.50 | +0.60 | 80.90 | +0.30 | +0.20 | 80.70 | +0.00 | +0.50 |
| 52 | 80.40 | +1 50 | +0.50 | 81.80 | +0.40 | +0.30 | 80.30 | +0.60 | +0.20 |
| 53 | 80.80 | +1 70 | +0.90 | 80.90 | +0.20 | +0.40 | 80.40 | +0.90 | +0 40 |
| Averages | 80.87 | +1.83 | +0.86 | 81.01 | +0.32 | +0.58 | 80.66 | +1.00 | +0.61 |
| **Yellowfin 28kg - #1 Cooking Grade** | | | | | | | | | |
| 83 | 81.60 | +1 20 | +0.70 | 81.60 | +0.40 | +0.10 | 80.50 | +1.20 | +0.50 |
| 84 | 80.80 | +1 80 | +0.70 | 80.90 | +0.40 | +0 40 | 80 70 | +1.40 | +0.80 |
| 85 | 80.90 | +2.70 | +1.10 | 80.90 | +0.00 | +0.30 | 80.80 | +1.70 | +0.70 |
| 86 | 80.50 | +1.50 | +0.70 | 80.60 | +0.20 | +0.20 | 81.00 | +1 50 | +0.50 |
| 87 | 81.50 | +1.40 | +0.40 | 82.60 | +0.30 | +0.00 | 81.50 | +0.90 | +0.30 |
| Averages | 81.06 | +1.72 | +0.72 | 81.32 | +0.26 | +0.20 | 80.90 | +1.34 | +0.56 |
| **Yellowfin 41 kg - #1 Cooking Grade** | | | | | | | | | |
| 192 | 8040 | +2.10 | +0.50 | 80.50 | +0.20 | +0 10 | 80.50 | +1.70 | +0.60 |
| 193 | 80.50 | +2.50 | +1.00 | 80.90 | +0.20 | +0.30 | 80.50 | +2.00 | +0.70 |
| 194 | 80.20 | +2.50 | +1.10 | 80.90 | +0.10 | +0.20 | 80.40 | +2.00 | +0.60 |
| 195 | 80.20 | +2.00 | +0.50 | 80.70 | +0.40 | +0.20 | 80.70 | +2.10 | +0.70 |
| 205 | 80.30 | +1.50 | +0.70 | 80.70 | +0.00 | +0.40 | 80.20 | +1.40 | +0.70 |
| 206 | 80.40 | +2.30 | +0.50 | 80.70 | +0.20 | +0.00 | 80.70 | +2.00 | +0.50 |
| 207 | 80.20 | +1.80 | +0.60 | 80.50 | +0.20 | +0.00 | 80.20 | +1.60 | +0.50 |
| Average8 | 80.30 | +2.10 | +0.70 | 80.70 | +0.16 | +0.17 | 80.46 | +1.82 | +0.61 |
| **Yellowfin 44kg - #1 Cooking Grade** | | | | | | | | | |
| 217 | 80.90 | +1.80 | +0.70 | 81.00 | +0.10 | +0.20 | 80.80 | +1.40 | +0.40 |
| 218 | 81.10 | +1.80 | +1.00 | 81.50 | +0.10 | +0.60 | 81.20 | +1.70 | +1.10 |
| 219 | 80.90 | +1 50 | +0.70 | 81.20 | +0.60 | +0.50 | 80.70 | +1.40 | +0.40 |
| 220 | 81.50 | +1.80 | +1.00 | 81.50 | +0.00 | +0.50 | 80.50 | +1.10 | +0. 70 |
| 221 | 80.70 | +1.50 | +0.70 | 80.50 | +0.30 | +0.00 | 80.20 | +1.20 | +0.30 |
| 227 | 80.80 | +1.00 | +0.60 | 81.20 | +0.20 | +0.50 | 80.90 | +2.00 | +0.80 |
| 230 | 80.80 | +1.70 | +0.90 | 80.50 | +0.30 | +0.20 | 80.50 | +0.80 | +0.50 |
| Averages | 80.95 | +1.68 | +0.80 | 81.05 | +0.22 | +0.35 | 80.68 | +1.37 | +0.60 |

Color Properties - Day One
Two Month Frozen and Defrosted

# Yellowfin and Bigeye Tuna

[illegible]or Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | 82.10 | 82.20 | 81.40 |
| Low | 80.10 | 79.60 | 80.00 |
| Average | **80.74** | **80.55** | **80.49** |

Red Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +3.50 | +1.00 | +2.40 |
| Low | +1.30 | +0.00 | +0.10 |
| Averages | **+2.15** | **+0.48** | **+1.70** |

Yellow Color Values

| | *CO* | Untreated | Tasteless |
|---|---|---|---|
| High | +1.50 | +1.30 | +1.50 |
| Low | +0.50 | +0.30 | +0.40 |
| Averages | **+0.95** | **+0.79** | **+0.85** |

Color Properties - Day Five
Two Month Frozen and Defrosted

# Yellowfin and Bigeye Tuna

## Light/Darkness Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | 82.30 | 82.60 | 81.60 |
| Low | 80.20 | 80.50 | 80.20 |
| Averages | 80.88 | 81.10 | 80.72 |

## Red Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +3.30 | +0.70 | +2.60 |
| Low | +1.00 | +0.00 | +0.00 |
| Averages | +2.00 | +0.31 | +1.47 |

## Yellow Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +1.40 | +1.00 | +1.60 |
| Low | +0.40 | +0.00 | +0.20 |
| Averages | +0.83 | +0.38 | +0.50 |

## Albacore Color Properties - Day One
## Two Month Frozen and Defrosted

| | CO Treated | | | Untreated | | | Tasteless Smoke | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample | Light | Red | Yellow | Light | Red | Yellow | Light | Red | Yellow |
| Albacore 31kg - #1 Cooking Grade | | | | | | | | | |
| 105 | 80.70 | +1 40 | +0.80 | 81.30 | +0.40 | +1.10 | 81.10 | +1.30 | +0.90 |
| 106 | 81.00 | +1.80 | +0.90 | 81.70 | +0.30 | +0.90 | 81.50 | +1.80 | +1.40 |
| 107 | 81.20 | +1.40 | +1.10 | 81.30 | +0.20 | +1.10 | 81.00 | +1.50 | +1.10 |
| 108 | 82.50 | +2.40 | +1.30 | 82.00 | +0.70 | +1.10 | 82.40 | +1.40 | +1.20 |
| 109 | 81.80 | +1.50 | +1.40 | 82.60 | +0.50 | +1.90 | 81.80 | +1.30 | +1.30 |
| 110 | 81.70 | +1.90 | +1.20 | 82.20 | +1.40 | +1.30 | 81.50 | +1.80 | +1.20 |
| Averages | 81.40 | +1.73 | +1.11 | 81.60 | +0.58 | +1.23 | 81.50 | +1.51 | +1.18 |

## Albacore Color Properties - Day Five
## Two Month Frozen and Defrosted

| | CO Treated | | | Untreated | | | Tasteless Smoke Treated | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample | Light | Red | Yellow | Light | Red | Yellow | Light | Red | Yellow |
| Albacore 31kg - #1 Cooking Grade | | | | | | | | | |
| 105 | 80.90 | +1.30 | +0.70 | 81.60 | +0.10 | +0.70 | 81.40 | +1.00 | +0.70 |
| 106 | 81.10 | +1 70 | +0.70 | 81.20 | +0.00 | +0.50 | 81.70 | +1.60 | +1.20 |
| 107 | 81.40 | +1.30 | +1.00 | 81.70 | +0.20 | +0.70 | 81.20 | +1.30 | +0.80 |
| 108 | 82.60 | +2.20 | +1.20 | 82.50 | +0.20 | +0.80 | 82.60 | +1.20 | +1.00 |
| 109 | 81.90 | +1.40 | +1.30 | 83.00 | +0.11 | +1.40 | 82.00 | +1.00 | +1.10 |
| 110 | 81.80 | +1.80 | +1.10 | 82.70 | +1.00 | +0.80 | 81.70 | +1.60 | +1.00 |
| Averages | 81.61 | +1.61 | +1.00 | 82.11 | +0.26 | +0.81 | 81.76 | +1.28 | +0.96 |

Color Properties - Day One
Two Month Frozen and Defrosted

# Albacore Tuna

## Light/Darkness Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | 82.50 | 82.60 | 82.40 |
| Low | 80.70 | 80.70 | 81.00 |
| Averages | 81.40 | 81.60 | 81.50 |

## Red Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +2.40 | +1.40 | +1.80 |
| Low | +1.40 | +0.20 | +1.30 |
| Averages | +1.73 | +0.58 | +1.51 |

## Yellow Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +1.40 | +1.90 | +1.40 |
| Low | +0.80 | +0.90 | +0.90 |
| Averages | +1.11 | +1.23 | +1.18 |

Color Properties - Day Five
Two Month Frozen and Defrosted

# Albacore Tuna

## Light/Darkness Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | 82.60 | 83.00 | 82.60 |
| Low | 80.90 | 81.20 | 81.20 |
| Averages | 81.60 | 82.11 | 81.76 |

## Red Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +2.20 | +1.00 | +1.60 |
| Low | +1.30 | +0.00 | +1.00 |
| Averages | +1.61 | +0.26 | +1.28 |

## Yellow Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +1.30 | +1.40 | +1.20 |
| Low | +0.70 | +0.50 | +0.70 |
| Averages | +1.00 | +0.81 | +0.96 |

**Salmon *Color* Properties - Day One**
**Two Month Frozen and Defrosted**

| | CO Treated | | | Untreated | | | Tasteless Smoke | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample | Llght | Red | Yellow | Llght | Red | Yellow | *Llght* | Red | Yellow |
| Salmon 3.1 kg - Japan "B" Grade | | | | | | | | | |
| *56* | 81.60 | +4.40 | t2.70 | 81.30 | +3.20 | +2.30 | 81.40 | +4.00 | +2.60 |
| 57 | 81.60 | +4.30 | +2.60 | 81.10 | +3.10 | +2.30 | 81.70 | +3.50 | +2.40 |
| Averages | 81.60 | +4.35 | +2.65 | 81.20 | +3.15 | +2.30 | 81.66 | +3.75 | +2.50 |

## Salmon Color Properties - Day Five
## Two Month Frozen and Defrosted

| | CO Treated | | | Untreated | | | Tasteless Smoke | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample | Light | Red | Yellow | Light | Red | Yellow | Light | Red | Yellow |
| Salmon 3.1kg - Japan "B" Grade | | | | | | | | | |
| 56 | 81.80 | +4.20 | +2.60 | 81.50 | +2.80 | +2.60 | 81.60 | +3.80 | +2.40 |
| 57 | 81.70 | +4.20 | +2.50 | 81.50 | +2.70 | +2.00 | 81.90 | +3.30 | +2.20 |
| Averages | 81.75 | +4.20 | +2.55 | 81.6 | +2.75 | +2.30 | 81.76 | +3.55 | +2.30 |

Color Properties - Day One
Two Month Frozen and Defrosted

# SALMON

## Light/Darkness Color Values

| | *CO* | Untreated | Tasteless |
|---|---|---|---|
| High | 81.60 | 81.30 | 81.70 |
| LOW | 81.60 | 81.10 | 81.40 |
| Averages | a1.60 | 81.20 | 81.55 |

## Red Color Values

| | *CO* | Untreated | Tasteless |
|---|---|---|---|
| High | +4.40 | +3.20 | +4.00 |
| Low | +4.30 | +3.10 | +3.50 |
| Averages | +4.35 | +3.15 | +3.75 |

## Yellow Color Values

| | *CO* | Untreated | Tasteless |
|---|---|---|---|
| High | +2.70 | +2.30 | +2.60 |
| Low | +2.60 | +2.30 | +2.40 |
| Averages | +2.65 | +2.30 | +2.50 |

Color Properties - Day Five
Two Month Frozen and Defrosted

# SALMON

## Light/Darkness Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | 81.80 | 81.50 | 81.90 |
| Low | 81.70 | 81.50 | 81.60 |
| Averages | 81.75 | 81.50 | 81.75 |

## Red Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +4.20 | +2.80 | +3.80 |
| Low | +4.20 | +2.70 | +3.30 |
| Averages | +4.20 | +2.75 | +3.55 |

## Yellow Color Values

| | CO | Untreated | Tasteless |
|---|---|---|---|
| High | +2.60 | +2.60 | +2.40 |
| Low | +2.50 | +2.00 | +2.20 |
| Averages | +2.55 | +2.30 | +2.30 |

# Appendix 6

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# Texture Measurement Results

# Texture Measurements
# Two Month Frozen and Defrosted

### Raw Texture

| Sample # | Untreated | Tasteless Smoke |
|---|---|---|
| 22 | 7.2 | 6.8 |
| 41 | 6.7 | 6.5 |
| 57 | 6.7 | 6.6 |
| 87 | 6.5 | 6.1 |
| 109 | 7.0 | 6.8 |
| 207 | 6.8 | 6.5 |
| 221 | 7.4 | 7.0 |
| 227 | 7.0 | 6.5 |
| **Averages** | **6.91** | **6.60** |

### Cooked Texture

| Sample # | Untreated | Tasteless Smoke |
|---|---|---|
| 22 | 7.5 | 7.0 |
| 41 | 7.0 | 6.8 |
| | 7.3 | 6.9 |
| 87 | 6.9 | 6.7 |
| 109 | 7.4 | 7.1 |
| 207 | 7.3 | 7.0 |
| 221 | 7.5 | 7.4 |
| 227 | 7.3 | 6.9 |
| Averages | 7.23 | 6.98 |

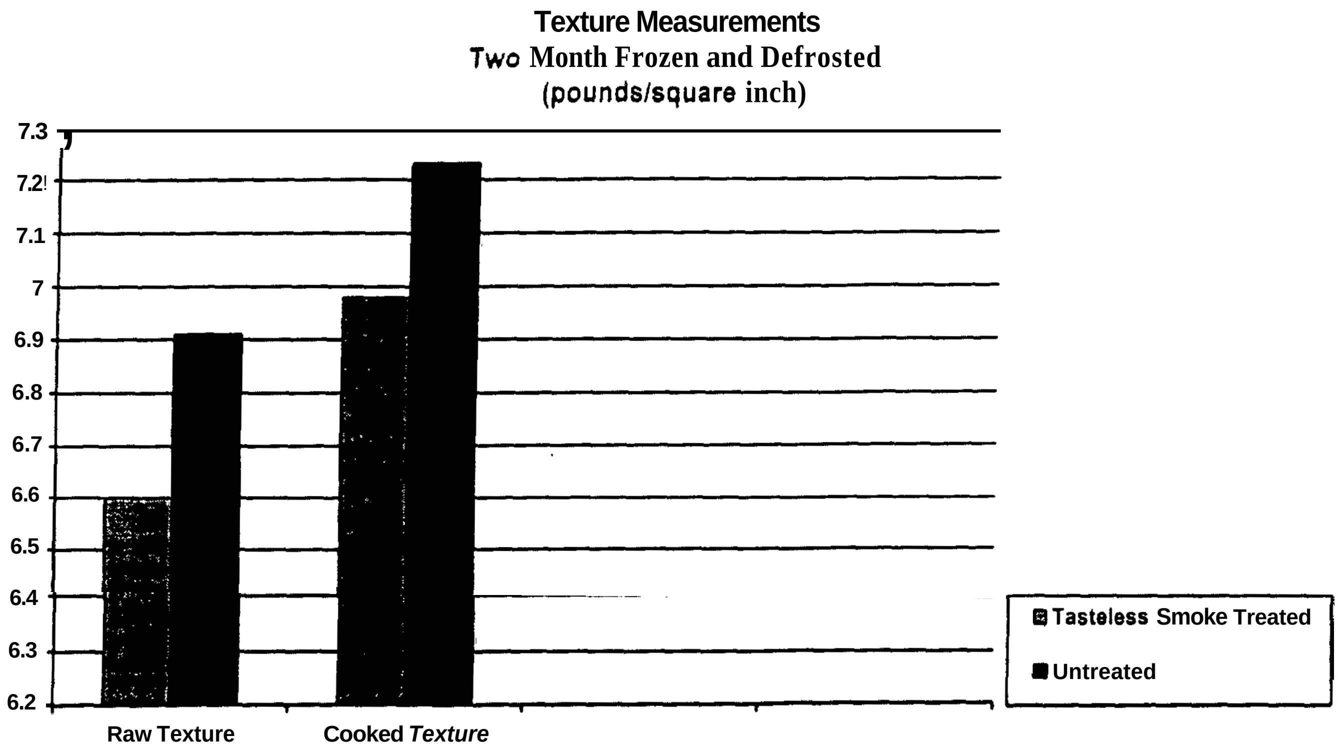
# Texture Measurements
# Two Month Frozen and Defrosted

### Raw Texture

| Sample # | Raw Smoke | Tasteless Smoke |
|---|---|---|
| 136 | 6.5 | 6.4 |
| 65 | 6.0 | 6.1 |
| 158 | 6.6 | 6.5 |
| Averages | 6.37 | 6.33 |

### Cooked Texture

| Sample # | Raw Smoke | Tasteless Smoke |
|---|---|---|
| 136 | 6.7 | 6.5 |
| 65 | 6.3 | 6.5 |
| 158 | 6.8 | 6.7 |
| Averages | 6.60 | 6.57 |



Texture Measurements
Two Month Frozen and Defrosted
(pounds/square inch)
7.3
7.2
7.1
7
6.9
6.8
6.7
6.6
6.5
6.4
6.3
6.2
Raw Texture
Cooked Texture
Tasteless Smoke Treated
Untreated


000072

## Texture Measurements
## Six Month Frozen and Defrosted

### *Raw* Texture

| Sample # | Untreated | Tasteless Smoke |
|---|---|---|
| 8 | 6.50 | 6.30 |
| **9** | 6.30 | 6.00 |
| *10* | ***6.60*** | **6.30** |
| 12 | 6.70 | 6.50 |
| **Averages** | **6.53** | **6.28** |

### Cooked Texture

| Sample # | Untreated | Tasteless Smoke |
|---|---|---|
| 8 | 6.70 | 6.60 |
| *9* | 6.70 | 6.30 |
| 10 | 7.10 | 6.90 |
| **12** | **7.10** | 6.70 |
| **Averages** | **6.90** | **6.63** |

# Appendix 7

# Aroma Intensity Raw Data

# Aroma Intensity Evaluations
# Two Month Frozen and Defrosted

### Raw Aroma Intensity

| Sample # | CO Treated | Untreated | Tasteless Smoke |
|---|---|---|---|
| 22 | 4 | 6 | 5 |
| 41 | 5 | 6 | 5 |
| 57 | 6 | 7 | 6 |
| 87 | 5 | 5 | 5 |
| 109 | 4 | 5 | 4 |
| 207 | 6 | 7 | 6 |
| 221 | 5 | 6 | 6 |
| 227 | 5 | 6 | 5 |
| **Averages** | **5.00** | **6.00** | **5.25** |

### Cooked Aroma Intensity

| Sample # | CO Treated | Untreated | Tasteless Smoke |
|---|---|---|---|
| 22 | 5 | 7 | 6 |
| 41 | 6 | 6 | 6 |
| 57 | 7 | 8 | 7 |
| 87 | 6 | 6 | 5 |
| 109 | 5 | 6 | 5 |
| 207 | 7 | 8 | 7 |
| 221 | 6 | 7 | 7 |
| 227 | 6 | 7 | 6 |
| **Averages** | **6.00** | **6.88** | **6.13** |

## Aroma Intensity Evaluations
## Two Month Frozen and Defrosted

### Raw Aroma Intensity

| Sample # | Raw Smoke | Tasteless Smoke |
|---|---|---|
| 136 | *5* | *5* |
| *65* | *6* | *5* |
| 158 | 5 | *6* |
| Averages | 5.33 | 5.33 |

### Cooked Aroma Intensity

| Sample # | Raw Smoke | Tasteless Smoke |
|---|---|---|
| I36 | *6* | *6* |
| *65* | 7 | *6* |
| 158 | *6* | 7 |
| Averages | 6.33 | 6.33 |

## Aroma Intensity Evaluations
## Six Month Frozen and Defrosted

### Raw Aroma Intensity

| Sample # | CO Treated | Untreated | Tasteless Smoke |
|---|---|---|---|
| 8 | 5 | 7 | 6 |
| 9 | 8 | 8 | 7 |
| 10 | 6 | 7 | 6 |
| 12 | 7 | 8 | 6 |
| Averages | 6.50 | 7.50 | 6.25 |

### Cooked Aroma Intensity

| Sample # | CO Treated | Untreated | Tasteless Smoke |
|---|---|---|---|
| 8 | 8 | 9 | 7 |
| 9 | 9 | 9 | 8 |
| 10 | 7 | 9 | 7 |
| 12 | 7 | 9 | 7 |
| Averages | 7.75 | 9.00 | 7.25 |

# Appendix 8

# pH Measurements Test

## pH Measurements
## Two Month Frozen and Defrosted

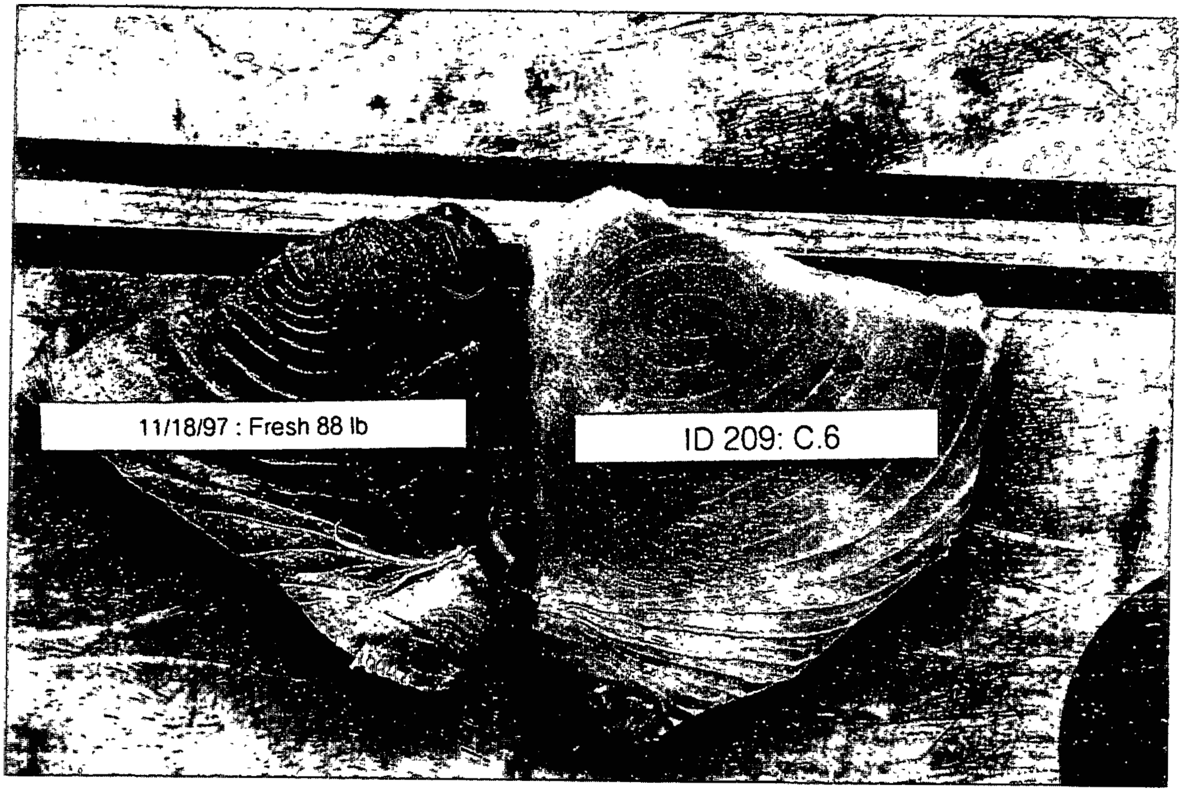
| Sample # | Untreated | Tasteless Smoke |
|---|---|---|
| 22 | 5.94 | 5.91 |
| 41 | 5.88 | 5.88 |
| 57 | 6.28 | 6.26 |
| 87 | 5.81 | 5.79 |
| 109 | 5.96 | 5.92 |
| 207 | 5.90 | 5.87 |
| 221 | 5.99 | 5.97 |
| 5.93 | 5.99 | 5.99 |
| Averages | 5.97 | 5.95 |

| Sample # | Raw Smoke Treated | Tasteless Smoke |
|---|---|---|
| 136 | 6.03 | 5.99 |
| 158 | 6.41 | 6.33 |
| 158 | 5.87 | 5.85 |
| Averages | 6.10 | 6.06 |

# Appendix 9

# Untouched Color Photographs

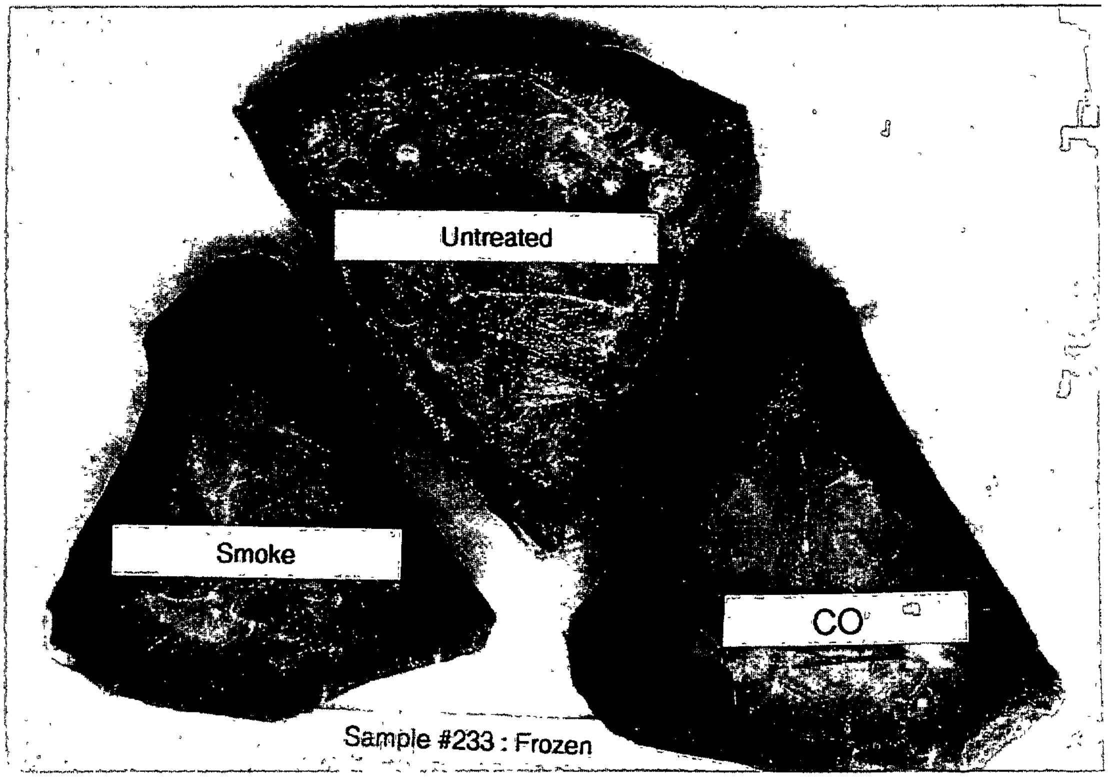
PHOTOGRAPH 1




PHOTOGRAPE 2

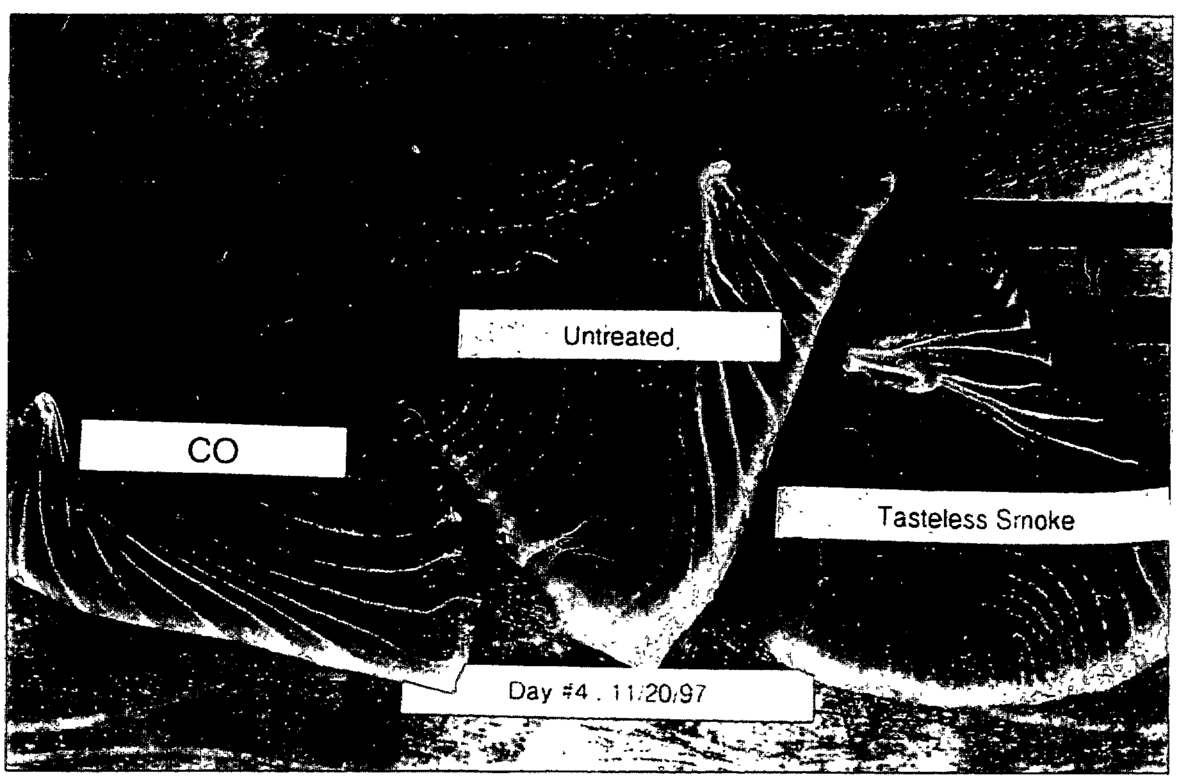
000081

PHOTOGRAPH - 3




PHOTOGRAPH - 4





# Appendix 10

## Data Demonstrating that Tasteless Smoke and Conventional Smoke have Comparable Effects on Tuna, Salmon and Albacore

# Raw Smoke vs. Tasteless Smoke Color Properties - Day One
## Two Month Frozen and Defrosted

## TUNA

Light/Darkness

| | Raw Smoke | Tasteless |
|---|---|---|
| High | 82.60 | 82.70 |
| Low | 82.00 | 81.70 |
| Average | 82.20 | 82.10 |

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +3.90 | +3.50 |
| | +2.90 | +2.90 |
| Average | +3.40 | +3.10 |

Yellow

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +2.10 | +1.90 |
| Low | +1.40 | +1.60 |
| Average | +1.77 | +1.72 |

## SALMON

Light/Darkness

| | Raw Smoke | Tasteless |
|---|---|---|
| High | 82.20 | 81.50 |
| Low | 81.80 | 81.50 |
| Average | 82.00 | 81.50 |

Red

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +3.90 | +3.60 |
| Low | +3.20 | +2.90 |
| Average | +3.55 | +3.25 |

Yellow

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +2.60 | +2.70 |
| Low | +2.20 | +2.70 |
| Average | +2.40 | +2.70 |

## ALBACORE

Light/Darkness

| | Raw Smoke | Tasteless |
|---|---|---|
| High | 82.90 | 82.90 |
| Low | 81.40 | 81.50 |
| Average | 82.00 | 82.00 |

Red

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +2.70 | +2.70 |
| Low | +2.10 | +1.40 |
| Average | +2.30 | +1.84 |

Yellow

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +1.70 | +1.80 |
| Low | +1.10 | +1.20 |
| Average | +1.38 | +1.43 |

000084

## Tasteless Smoke vs. Raw Smoke Color Properties - Day Five
## Two Month Frozen and Defrosted

# TUNA

Light/Darkness

| | Raw Smoke | Tasteless |
|---|---|---|
| High | 82.80 | 83.00 |
| Low | 82.30 | 81.90 |
| Average | 82.52 | 82.35 |

Red

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +3.60 | +3.30 |
| Low | +2.80 | +2.60 |
| Average | +3.15 | +2 82 |

Yellow

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +2.00 | +1.60 |
| Low | +1.10 | +1.40 |
| Average | +1.57 | +1.47 |

# SALMON

Light/Darkness

| | Raw Smoke | Tasteless |
|---|---|---|
| High | 82.40 | 81.60 |
| Low | 82.30 | 81.60 |
| Average | 82.00 | 81.60 |

Red

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +3.50 | +4.20 |
| Low | +3.00 | +2.80 |
| Average | +3.25 | +3 25 |

Yellow

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +2.50 | +2.50 |
| Low | +2.40 | +2.10 |
| Average | +2 45 | +2.40 |

# ALBACORE

Light/Darkness

| | Raw Smoke | Tasteless |
|---|---|---|
| High | 83.00 | 83.00 |
| Low | 81.70 | 81.70 |
| Average | 82.20 | 82 23 |

Red

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +2.50 | +2.60 |
| Low | +1.90 | +1.20 |
| Average | +2.15 | +1.95 |

Yellow

| | Raw Smoke | Tasteless |
|---|---|---|
| High | +1.40 | +1.70 |
| Low | +0 90 | +1 .00 |
| Average | +1.18 | +1.26 |

# Appendix 11

# Panel Results Demonstrating Tasteless Smoke Treated Tuna Has Properties Different From CO Treated Tuna

# SEAFOOD SAMPLE ANALYSIS

Date 9·12·97 Technician Name/names S. FISHER, N. NUKWATNI

Sample Procedure Informaton:

Sample lot # CV1001 Species ALBACORE Production code NA

Sample Code CO Test Applied 18 HR CO TREAT – FROZEN

Sample Code UNT Test Applied CONTROL – FROZEN

Sample Code SMOKE Test Applied 18 HR SMK TREAT – FROZEN (TASTELESS FILTERED SMK)

| Fresh____<br>Fzn<br>Thawed X<br># Days Fresh____<br># Days Thawed 1<br>Sample Code<br>AB | COLOR<br>A. Red/pink natural.<br>B. Slightly faded red/pink.<br>C. Bright unnatural red-pink.<br>D. Brown, grey or colorless. | RAW TASTE<br>A. Natural fish taste.<br>B. Flat, little or no tatse<br>C. Slightly off, fishy or "freezer" taste.<br>D. Very fishy, very off. | COOKED TASTE<br>A. Natural fish taste.<br>B. Flat, little or no taste<br>C. Slightly fishy or "freezer" taste.<br>D. Very fishy, very off | TEXTURE<br>A. Firm, resilient.<br>B. Slightly soft, dimples when pressed.<br>C. Md. soft/ seperation<br>D. Mushy, broken. | DE-COMP<br>A. Pleasant natural fish smell.<br>B. Slightly fishy or sulpher smell.<br>C. Fishy/sulph-erous<br>D. Spoiled | COMMENT<br>(SEE PHOTOS) |
|---|---|---|---|---|---|---|
| CO | C | B | B | A | A | |
| UNT | D | C | C | B | A | |
| SMOKE | A | A | A | B | A | |
| | | | | | | |
| DAY 3: | | | | | | |
| CO | C | NA | B | B | B* | *NOT SAME "CHEMICAL" SMELL |
| UNT | D | NA | C | C | B | |
| SMOKE | B | NA | C | C | B | |
| | | | | | | |
| | | | | | | |

9-14

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# SEAFOOD SAMPLE ANALYSIS

Date 9.12.97 Technician Name/names S. FISHER, N. NUKWATNI

Sample Procedure Informaton:

Sample lot # CV1002 Species YELLOWFIN Production code NA

Sample Code YFN Test Applied 18-24 HR SMOKE - FROZEN (TASTELESS FILTERED SMOKE)

Sample Code YFCO Test Applied 18-24 HR CO - FROZEN

Sample Code X Test Applied X - NA

| Fresh ____ Frzn Thawed X # Days Fresh ____ # Days Thawed 1 Sample Code YF | COLOR A. Red/pink natural B. Slightly faded red/pink. C. Bright unnatural red-pink D. Brown, grey or colorless. | RAW TASTE A. Natural fish taste. B. Flat, little or no taste. C. Slightly off, fishy or "freezer" taste D. Very fishy, very off. | COOKED TASTE A. Natural fish taste B. Flat, little or no taste C. Slightly fishy or "freezer" taste. D. Very fishy, very off. | TEXTURE A. Firm, resilient B. Slightly soft, dimples when pressed C. Md soft/ seperation. D. Mushy, broken | DE-COMP A. Pleasant natural fish smell. B. Slightly fishy or sulpher smell C. Putrid/sulphurous. D. Spoiled | COMMENT (SEE PHOTOS) |
|---|---|---|---|---|---|---|
| YFN | A. | A | A | B | A | |
| YFCO | C | B | B | A | A | |
| | | | | | | |
| 9-14 DAY 3: | | | | | | |
| YFN | C3 | NA | A | C | B | |
| YFCO | C * | NA | B | B | A (CHEMICAL, PLASTIC) | * SLIGHT FADING STILL UNNATURAL PINK/RED |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

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# Appendix 12

# Residual Carbon Monoxide Level Test Results

## Japan Test Results
## Residual CO Measurements

**Results: Carbon Monoxide Mg/kg**

| Lot Number | CO Treated | Untreated | Tasteless Smoke |
|---|---|---|---|
| 25 | 1500 | 49 | 1000 |
| 88 | 240 | 40 | 400 |
| 215 | 470 | 30 | 550 |
| 224 | 1400 | 32 | 490 |
| 6 | 2100 | 43 | 1400 |
| Averages | 1142 | 38.8 | 768 |

# United States Test Results
# Carbon Monoxide by GC/FID with Catalyst

| Lot Number | CO Treated | Untreated | Tasteless Smoke |
|---|---|---|---|
| 27 | 682 | 56 | 416 |
| 60 | 76 | 8 | 101 |
| 223 | 390 | 18 | 174 |
| 4 | 335 | 35 | 280 |
| Averages | 370.75 | 29.25 | 242.75 |

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AM

# HOGAN & HARTSON
L.L.P.

MARTIN J. HAHN
PARTNER
· (202) 637-5926
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March 11, 1999

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555 THIRTEENTH STREET, NW
WASHINGTON, DC 200041109
TEL (202) 637-5600
FAX (202) 837-5910

*BY HAND DELIVERY*

Paulette Gaynor, Ph.D.
Office of Premarket Approval (HFS-215)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, D.C. 20204

**Re: Revised GRAS Exemption Claim for Tasteless Smoke**

Dear Dr. Gaynor:

As we discussed during our telephone conversation on March 5, we are submitting a revised notification which clarifies that our notification establishes that tasteless smoke is GRAS based on scientific procedures as corroborated by common use in foods. We are submitting three copies of this cover letter, the revised GRAS exemption claim and an original and two copies of the notification. We are not, however, resubmitting copies of the appendices. It is our understanding that the agency is willing to use the appendices found in the .February 18, 1999 submission.

If you have any questions, please contact me at the above phone number and address.

Sincerely,

Martin J. Hahn

Enclosures

1999 MAR 17 A 10: 42

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# HOGAN & HARTSON
L.L.P.

1999 MAR 11 A 10: 43

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FAX (202) 657-5910

***BY HAND DELIVERY***

Office of Premarket Approval **(HFS-215)**
Center for Food Safety and Applied Nutrition
Food and Drug Administration
**200** C Street SW
Washington, D.C. **20204**

**Re: GRAS Exemption Claim for Tasteless Smoke**

To Whom it May Concern:

On behalf of our client, Hawaii International Seafood Inc., Honolulu International Airport, P.O. Box **30486,** Honolulu, Hawaii **96820,** we submit this notification which contains data and information establishing that tasteless smoke is generally recognized as safe (GRAS). We enclose an original and two copies of this notification for your review.

Tasteless smoke is used to protect the taste, aroma and color of seafood at levels sufficient to accomplish this purpose. Tasteless smoke is merely a purified version of the filtered smoke that has been used for decades in the processing of seafood. Although we believe that sufficient data exist to support the GRAS status of tasteless smoke on the basis of common use in foods, this submission establishes that tasteless smoke is GRAS on the basis of scientific procedures as corroborated by common use in foods. In the preamble to the proposal that would establish the GRAS notification, the Food and Drug Administration (FDA) recognized that in certain instances the GRAS status of a food ingredient could be established by demonstrating that it is substantially equivalent in composition to, and has substantially equivalent characteristic properties to, a known GRAS ingredient. Tasteless smoke meets these criteria because it is substantially equivalent to, and has substantially equivalent characteristic properties to, filtered smoke, a GRAS ingredient that has been used by the seafood industry for over **90** years.

Because tasteless smoke is GRAS, it is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act. Additional data and information supporting the GRAS status of tasteless smoke, including the raw data, will be made available for the Food and Drug Administration (FDA) review upon request.

If you have any questions, please contact me at the above phone number and address.

Sincerelv.

Martin J. Hahn

Enclosures

**Hawaii International Seafood, Inc.**
**GRAS Notification Summary**
**For the Use of Tasteless Smoke**
**In the Preservation of Seafood**
**March 1999 1/**

# I. DESCRIPTION OF THE SUBSTANCE

## A. Common or Usual Name

The common or usual name is tasteless smoke. Tasteless smoke is an appropriate name because the product is manufactured by filtering conventional smoke. Tasteless smoke is generated by combusting wood chips in contact with a heated surface, capturing the smoke and running it through a filtration and purification process that removes the particulate matter and many of the flavor components found in conventional smoke. Tasteless smoke is merely a super-filtered version of the conventional smoke that has been used for decades in the cold-smoking of fish.

## B. Chemical Name

There are numerous chemicals in tasteless smoke just as there are numerous different chemicals in smoke. The primary components in tasteless smoke are nitrogen ($N_2$), oxygen ($O_2$), carbon monoxide (CO), carbon dioxide ($CO_2$), methane ($CH_4$), aromatic phenols and hydrocarbons.

## C. CAS Number

There is no **CAS** number for tasteless smoke.

## D. Empirical Formula

There is no empirical formula for tasteless smoke per se. There are, however,'empirical formulas for the constituents found in tasteless smoke. For example, the primary components in tasteless smoke are nitrogen ($N_2$), oxygen ($O_2$), carbon monoxide (CO), carbon dioxide ($CO_2$), and methane ($CH_4$). There are also trace levels of different aromatic phenols and hydrocarbons.

## E. Structural Formula

There also is no structural formula for tasteless smoke per se. As discussed, above, there are structural formulas for the primary components in the

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1/ This submission incorporates by reference the appendices submitted in the February 1999 notification.

tasteless smoke (*i.e.*, nitrogen ($N_2$), oxygen ($O_2$), carbon monoxide (CO), carbon dioxide ($CO_2$), and methane ($CH_4$)).

### F. Specifications for Food Grade Material

The following specifications are established for the tasteless smoke:

| | |
|---|---|
| Carbon Dioxide | 7-25% |
| Carbon Monoxide | 7-30% |
| Aromatic Phenols (gaseous vapor) | 10 ppb to 15.6 ppm |
| Hydrocarbons ($C_5$ to $C_{10}$) | 2000 to 6000 ppm (volume) |
| Hydrocarbons ($C_2$ to $C_4$) | 2000 to 6000 ppm (volume) |
| Combustion Temperature | <850 °F |

The specification for the combustion temperature has been established to reduce the formation of deleterious compounds in the smoke. The formation of deleterious polynuclear aromatic hydrocarbons (PAHs) and the oxidation of organic vapors, including both condensable organic compounds as well as volatile organic compounds (VOCs) can be prevented by combusting below 850 °F (454 °C). Although most of these VOCs are removed by the filtration and purification process, the 850 °F specification is nonetheless established to minimize the formation of these undesirable compounds.

### G. Quantitative Composition

Tasteless smoke has the following quantitative composition:

| | |
|---|---|
| Carbon Dioxide | 7-25% |
| Carbon Monoxide | 7-30% |
| Aromatic Phenols (gaseous vapor) | 10 ppb to 15.6 ppm |
| Hydrocarbons ($C_5$ to $C_{10}$) | 2000 to 6000 ppm (volume) |
| Hydrocarbons ($C_2$ to $C_4$) | 2000 to 6000 ppm (volume) |
| Nitrogen and Oxygen | 45-86% |
| Methane | <15% |

### H. Manufacturing Process

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Smoke is generated by burning an organic, food grade smoking material below 850 °F (454 °C) in a smoke generator. This conventional smoke is then passed through a proprietary filtration process. This filtration process removes the particulate matter and the taste components from the vapor phase of the smoke. The filtered smoke is then allowed to flow directly into a smoking chamber or it is collected and stored for use at a later time.

The seafood is placed in a smoking chamber where the temperature is maintained just slightly over freezing. 2/ The chamber is flooded with tasteless smoke and the seafood will remain in the smoking chamber until the smoke has had sufficient time to penetrate the tissue and impart its preservative effect. The "smoking" time will vary depending on several factors such as the species, type of cut and thickness of the cut. Through the expenditure of considerable resources, Hawaii International Seafood has developed an internal data base that identifies the amount of time a particular cut of seafood needs to be exposed to the tasteless smoke. Hawaii International Seafood developed this data base by exposing cuts of the seafood to tasteless smoke for different times. Hawaii International Seafood performed organoleptic and other evaluations of the product to assess how much time is needed for the tasteless smoke to impart its preservative characteristics.

After the product has been exposed to the tasteless smoke for the requisite amount of time, it is removed from the smoking and cryogenically frozen. The tasteless smoke treated seafood can be stored for up to one year. The treated product can be quick or slow thawed with little degradation of the taste, aroma, texture or color of the treated seafood.

## II. TASTELESS SMOKE IS GRAS

### A. Date When Use Began For Smoke

#### 1. Conventional Smoke Has Been Used for Centuries

Smoke has been used for centuries in the preservation of seafood. The preservation effect came from not only the components in the smoke, but also from the heating and drying associated with the smoking process. With the advent of refrigeration, the use of smoke as the primary means to preserve seafood became less important, although smoked seafood continues to have a longer shelf life than their non-smoked counterparts.

#### 2. Filtered Smoke Has Been Used for at Least 90 Years

Tasteless smoke is derived by filtering and purifying conventional smoke. Meat and seafood processors have been using purified smoke for at least 90 years. **A** 1908 U.S. patent discusses a device for curing edible matter comprised of a

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2/ Seafood can be maintained fresh and unfrozen for two to three weeks at temperatures of **27** to **32** °F (**-0.3** to 0°C). It does not freeze at these temperatures due to the salt content in the meat.

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curing compartment, a smoke supply source, and a combined smoke cooling, purifying, and drying chamber where a portion of moisture and carbon soot condenses on the walls of the chamber. 3/ This method and apparatus manufactures filtered smoke with substantially all odor and taste imparting particulate matter removed from the particulate phase of the smoke leaving only the vapor phase.

In addition, many meat and seafood processors have used a number of systems to eliminate substantially all of the particulate matter from smoke. The pollutants in the particulate phase of smoke are typically filtered. Many methods are used to filter out the tar, soot, ash, char and other microscopic particulates, such as tar settling systems, baffling systems, and washing systems in the line from the smoke generator to the smoking chamber. In addition, cooling and storage reduces the concentrations of phenolic particulate through settling. Some of these filtering methods remove substantially all the tar and particulate from wood smoke leaving only the gaseous vapor phase which produces the characteristic smoke flavor. The amount of particulate mattered filtered from the smoke can range from 0 to 100%. Filtered smoke, therefore, has been used to treat seafood since well before 1958.

### 3. Filtered Smoke Has Been Used on Raw Fish at Cold Temperatures for Over 70 Years

Fish has been both hot and cold smoked for generations. A filtered smoke has been used to cold smoke salmon in Europe and North America for decades. Salmon is treated with the filtered smoke to preserve its color and texture and to impart a light smoke taste. Tasteless smoke is a super-filtered version of the same smoke that has been used in salmon smoke houses for decades.

Although it is difficult to state precisely when the fish industry first used the cold smoking process, our review has established that this process has been practiced for at least 70 years. For example, in the U.S. Pacific Northwest, Josephson's Smokehouse & Specialty Seafood Company has been cold smoking high quality Pacific Chinook Salmon since 1920. In Oregon, Sportsmen's Cannery & Smokehouse, established in 1955, utilizes a cold smoked process. In California, the Los Angeles Smoking & Curing Company (LASCCO) has been cold smoking seafood since 1921. All three of these examples of cold smoking of salmon prior to 1958 show the use of filtered wood smoke to fix salmon color and texture. In addition, Josephson's and LASCCO have cold smoked albacore tuna as well. 4/

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3/ U.S. Patent 889,828 to Trescott (1908).

4/ *See* Appendix 1 for testimonials which establish that seafood companies have cold-smoked fish prior to 1958.

## B. Filtered Smoke is GRAS

Filtered smoke is generally recognized as safe (GRAS). Although FDA has not specifically listed or affirmed it as GRAS, FDA is not required to do so under the Federal, Food, Drug and Cosmetic Act. Indeed, FDA specifically recognizes in its GRAS regulations that it is "impracticable to list all substances that are generally recognized as safe for their intended use." 5/ Filtered smoke is GRAS based on common use in foods because it has been used prior to 1958. The GRAS status of conventional (filtered) smoke is also supported by the numerous food standards and other FDA regulations that specifically recognize the use of smoke as an ingredient in foods. For example, the standard of identity for canned tuna specifically allows the product to be smoked. 6/

In addition, there are numerous cheese standards of identity that specifically authorize for the smoking of cheese, including the standards for colby cheese, cold-pack cheese, cold-pack cheese food, pasteurized process cheese, pasteurize process cheese food, pasteurized process cheese spread, and provolone. 7/ The GRAS status of conventional wood smoke is further supported by its listing as an approved ingredient that may be added to meat and poultry products. 8/

## C. Tasteless Smoke is Substantially Equivalent to Conventional Smoke

Tasteless smoke is substantially equivalent to conventional smoke. There is tremendous variability in the composition of smoke and the components of tasteless smoke are within ranges ordinarily found in conventional smoke. The source of the wood, the combustion temperature, the amount of oxygen in the combustion chamber, and the filtration process, if any, are examples of the factors that will have an impact on the final composition of wood smoke. A publication of the Environmental Protection Agency (EPA) demonstrates the tremendous variability in the composition of wood smoke, particularly with regard to the levels of carbon monoxide and carbon dioxide. 9/ This publication identifies the various components in smoke and reports the grams of such components produced from one kilogram of wood. The chart below compares the amount of carbon monoxide and

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5/ 21 CFR § 182.1(a).

6/ 21 CFR § 169.190(a)(3)(v).

7/ 21 CFR § § 133.118(d)(1), 133.123(b)(1), 133.124(b), 133.169(b), 133.173(b), 133.17503) and 133.181(a)(3), respectively.

8/ 9 CFR §§ 318.7(c)(4), 381.147(c)(4).

9/ See Appendix 2.

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carbon dioxide generated from one kilogram of wood in conventional and tasteless smoke:

| | **Tasteless Smoke** | | **Conventional Smoke** | |
|---|---|---|---|---|
| **Carbon Monoxide** | **15-66** g/kg wood | | **80-370** g/kg wood | |
| **Carbon Dioxide** | **15-55** g/kg wood | | *70-200* g/kg wood | |
| **Ratios CO/CO2** | Low **Range**<br>**1** | **High Range**<br>**1.1** | Low **Range**<br>**1.1** | High **Range**<br>1.85 |

This table demonstrates that the manufacturing process for tasteless smoke has not been altered to increase the carbon monoxide or carbon dioxide emissions in the finished product. These data demonstrate that the levels of carbon monoxide and carbon dioxide generated from one kilogram of wood are .actually less than that generated in conventional smoke. This difference is likely attributable to the controlled, proprietary conditions under which the wood is combusted.

In addition, a comparison of the carbon monoxide/carbon dioxide ratios reviews that tasteless smoke actually contains a lower percentage of carbon monoxide than conventional smoke. There is a tremendous variability in the carbon monoxide and carbon dioxide concentrations of both tasteless and conventional smoke. On the lower end of this range, both tasteless smoke and conventional smoke have essentially equal quantities of carbon monoxide and carbon dioxide. On the upper end of the range, however, conventional smoke can have up to **1.85** times the level of carbon monoxide than carbon dioxide while tasteless smoke has comparable levels of carbon monoxide and carbon dioxide. The carbon monoxide content of tasteless smoke, therefore, has not been increased through the manufacturing process.

*Also* worth mentioning is that the above chart provides compositional information on unfiltered, conventional smoke. Tasteless smoke is even closer in composition to the filtered smoke which has been used for decades in the seafood industry. The process used to manufacture tasteless smoke is comparable to that used to manufacture filtered smoke except the smoke continues to run through additional filters that remove additional quantities of the same components that are removed from filtered smoke. It is estimated that the manufacturing process for tasteless smoke removes only 0.07 percent, by weight, of the components found in filtered smoke.

### D. The Components of Tasteless Smoke and Conventional Smoke are Found in Comparable Levels in Seafood Treated with These Products

Seafood treated with tasteless and conventional smoke have comparable levels of carbon monoxide, carbon dioxide, aromatic phenols, and hydrocarbons. Hawaii International Seafood smoked Albacore, Salmon, and Yellowfin with conventional smoke and tasteless smoke. An independent laboratory analyzed the products and the results of this analysis can be found in Appendix 3.

These data show significant differences in carbon monoxide and carbon dioxide levels in samples subjected to identical conditions. For example, the quantity of carbon dioxide found in Albacore treated with tasteless smoke ranged from approximately 2400 to 7900 and the quantity of carbon dioxide found in Salmon treated with raw smoke ranged from approximately 5,000 to 16,000. The levels of carbon monoxide in Albacore treated with tasteless smoke ranged from 19 to 24 while the levels found in conventionally smoked Albacore ranged from 23 to 52. These data reveal that the seafood treated with tasteless smoke and conventional smoke had comparable levels of carbon monoxide, carbon dioxide, $C_2$ to $C_4$ hydrocarbons, and phenols. The results did show slightly higher levels of the $C_4$-$C_{10}$ hydrocarbons in the tasteless smoke treated products, but a statistical analysis revealed no significant difference in these numbers. The use of tasteless smoke, therefore, is expected to result in levels of carbon monoxide, carbon dioxide, hydrocarbons and phenols comparable to that found in seafood treated with conventional smoke.

### E. Tasteless Smoke is GRAS

FDA recognizes in the preamble to the proposal that would establish the GRAS notification process that the concept of substantial equivalence has applicability to the technical element of a GRAS determination. 10/ According to FDA, the **GRAS** status of a substance can be established in some instances when the ingredient has a (1) substantially equivalent composition and (2) substantially equivalent characteristic properties, to that of a known GRAS ingredient. 11/ Tasteless smoke meets both of these criteria.

Data in this petition establish that tasteless smoke is substantially equivalent in composition to filtered smoke, which is a GRAS ingredient based on common use in foods. Tasteless smoke is generated from wood--the same starting

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10/ 62 Fed. Reg. 18938, 18945 (April 17, 1997).

11/ *Id.*

material used to make conventional smoke. There is a tremendous variability in the composition of conventional smoke and the primary constituents of tasteless smoke are within or below this "normal range."

Tasteless smoke also is manufactured and used in a manner consistent with practices that have been used by the seafood industry for many years prior to 1958. Tasteless smoke is manufactured by subjecting filtered smoke to another filtration step. The filtration step used by Hawaii International Seafood removes the same constituents that are removed during the conventional filtration process, although they are removed to a greater degree. This filtration step removes only 0.07 percent, by weight, of the taste- and odor-imparting chemicals found in the filtered smoke. Nothing is added to the tasteless smoke (except air--which is also found in conventional smoke). These compositional similarities establish that tasteless smoke is substantially equivalent to filtered smoke.

The characteristic properties and intended use of tasteless smoke are also substantially equivalent to filtered smoke. Tasteless smoke is applied at refrigerated temperatures, a practice that has been used by the seafood industry for many years prior to 1958. One of the purposes of cold smoking is to preserve the taste, aroma and texture of the product. Tasteless smoke is applied for this same intended use. In addition, data demonstrate that carbon monoxide, carbon dioxide, phenols and hydrocarbons (*i.e.,* the components of tasteless smoke for which specifications are established) are found at comparable levels in seafood that is cold-smoked with conventional and tasteless smoke.

### 1. Experts Have Reviewed the Data on Tasteless Smoke and Concluded that it is GRAS

Dr. Joseph Maga, Director of the Department of Food Science and Human Nutrition at Colorado State University has reviewed the tasteless smoke process and concluded that tasteless smoke is GRAS. Dr. Maga offered the following comments in this regard:

> The use of various smoke preparations (smoke vapor, liquid smoke extracts) have been routinely used in food preparation for centuries / decades. In most operations the particulate phase in both gaseous and liquid smoke preparations is routinely removed by various physical means such as filtration, sedimentation, and electrostatic precipitation to name a few. Your "Tasteless" smoke purification is simply an extension of traditional smoke purification. The resulting product does not have anything added and all components present in the product were originally present in smoke.

Additional experts in the area of smoking technology also have reviewed the process and concluded that tasteless smoke is GRAS. The letters from these experts can be found in Appendix **4.** The names, addresses and titles of the experts who have reviewed the process and concluded that tasteless smoke is GRAS are identified below:

Dr. Joseph Maga
Director
Department of Food Science and Human Nutrition
Colorado State University
Fort Collins, Colorado **80523-1571**

Dr. Steven D. Hoyt
President
Environmental Analytical Services, Inc.
**3421** Empresa, Suite A
San Luis Obispo, California 93401

Robert Hanson
Technical Director
Alkar, Inc.
932 Development Drive
P.O. **Box 260**
Lodi, Wisconsin **53555**

### 2. Tasteless Smoke Does Not Present the Potential Health Risks of Conventional Smoke Because the Carcinogenic Impurities Are Filtered Out and Removed

Tasteless smoke does differ from unfiltered conventional smoke in that all of the particulate matter and most of the flavor- and odor-imparting components have been removed. Also removed from tasteless smoke are the highly toxic and potentially carcinogenic compounds found in conventional smoke.

FDA recognizes that conventional smoke can be a source of carcinogenic impurities such as Benzo[a]pyrene (BaP) and other polynuclear aromatic hydrocarbons (PAHs). 12/ Tasteless smoke does not present the same potential health risks of conventional smoke because carcinogenic impurities are filtered out and removed. The super-purifying process of producing tasteless smoke removes any remaining particulate matter from the particulate phase and reduces the phenolic level of the gaseous phase below the odor and taste threshold. 13/

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12/ Food Additives Analytical Manual -- Volume 11, "Polynuclear Aromatic Hydrocarbons" (1987).

13/ The odor threshold for the vapor in smoke is **10.4** ppm, while the taste threshold is 2.3 ppm. Daun, H., Lebensm, Wiss. Technol. **5,102** (1972).

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### F. Intended Use

The tasteless smoke is intended to be used on raw seafood, such as tuna and salmon, before it is frozen. The tasteless smoke is added to preserve the taste, aroma, texture and color of the frozen seafood. As will be discussed in more detail below, without the addition of tasteless smoke, frozen tuna and other red-meat seafood is prone to browning, the development of off odors and decreased palatability during freezing.

### *G*. Limitations

There are no limitations on the use of tasteless smoke other than those imposed by good manufacturing practices. Hawaii International Seafood does limit the use of tasteless smoke to higher grades of tuna (*i.e.,* Japan B grade for frozen sashimi tuna and No. 1 U.S. cooking grade for frozen tuna steaks). This limitation assures that only higher quality tuna will be subjected to treatment with tasteless smoke. In addition, the grade of the tuna that is treated with the tasteless smoke is declared voluntarily on the label of the product.

## 111. EFFICACY DATA

### A. Background

#### 1. **Color** Physiology

The pigments in meat and in some species of seafood, such as tuna, consist largely of two proteins: hemoglobin, the pigment of the blood, and myoglobin, the pigment of the muscles. In well bled muscle tissue, up to 80 to 90 percent of the total pigment is myoglobin. The myoglobin molecule contains a globular protein portion (*i.e.,* globin) and a nonprotein heme ring. The heme ring contains an iron ion. The color of the heme ring and of the myoglobin molecule, is partially dependent on the oxidative state of the iron within the heme ring.

The quantity of myoglobin within the tissue and the intensity of the color varies depending on species, age, sex, muscle and physical activity. Species differences are apparent when comparing the lighter color of swordfish with the dark red color of tuna or the lighter color of pork with the darker color of beef. The impact **of** age is most apparent by comparing the lighter color of veal with the darker color of beef. There are also differences within species in that some tuna will have a higher quantity of myoglobin in the muscle tissue than other tuna. These intraspecies differences account for the variability in color of tuna steaks that are cut from different fish.

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The color of the meat is affected by the quantity of myoglobin in the tissue and by the oxidative state of the iron in the myoglobin. When the meat is first cut, the flesh has a dark red almost purple color, which is the color of myoglobin. The myoglobin.easily reacts with the oxygen in the air and forms oxymyoglobin which has a bright red color. When the oxymyoglobin is held in a conventional frozen environment, the iron ion in it is prone to oxidation and forms metmyoglobin, which has an undesirable brown color. The oxidized iron can also adversely effect the taste and smell of the product in that it leads to the oxidation of unsaturated fatty acids in seafood, thus generating volatile organic compound gases that produce undesirable smells and flavors.

The myoglobin can combine with substances other than oxygen and form compounds that are more stable at conventional frozen temperatures than oxymyoglobin. Of primary importance here are the reactions between myoglobin and the components in conventional smoke and tasteless smoke, carbon monoxide, nitric oxide, and nitrogen dioxide. In the presence of smoke and tasteless smoke, the myoglobin will form carboxymyoglobin, nitric oxide myoglobin, or nitrogen dioxide myoglobin, all of which are red.

The common curing agents, nitrates and nitrites, are sources of nitric oxide and lead to the formation of nitric oxide myoglobin. Curing a product with nitrates fixes color and preserve freshness, in part, by preventing oxidation of the oxymyoglobin into metmyoglobin. It is the FDA position that substances which "fix" or stabilize an existing color rather than add new colors are not color additives. This position is well settled and has been upheld by the courts. 14/

### 2. Impact of Freezing on Color of Fish

Freezing has an adverse impact on the color of tuna and other species of fish. The environment of conventional freezers with temperatures between 0 and -30°F (-18 to -34° C) facilitates the development of metmyoglobin in frozen tuna and other species. Observable browning in frozen tuna is generally noticed after two months of freezing. 15/ The oxidation of the oxymyoglobin into metmyoglobin decreases the acceptability of the frozen tuna because of the undesirable off-brown color and of the off-odors that develop. Consequently, frozen red meat fish distributed in the United States is prone to the adverse effects of oxidation unless it has been treated to prevent such oxidation.

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14/ *Public Citizen v. Hayes*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,161 (D.D.C. 1982) (nitrites "fix" the red color of meats and therefore are not color additives).

15/ Maga, Color Properties Test Results for Untreated Two Month Frozen and Thawed Tuna Samples (Appendix 5).

The oxidation of the oxymyoglobin can be prevented by maintaining the frozen seafood at super cold freezing temperatures below -76 °F. The use of these super cold temperatures is common in Japan which has an infrastructure that utilizes super cold freezers in the manufacturing and distribution system. Holding sashimi tuna at these super low temperatures is very effective in maintaining the natural bright red color of the flesh for up to one year. This technology is not widely utilized in the United States and the current processing and distribution channels lack the capabilities to maintain seafood at temperatures below -76 °F. Given the prohibitively expensive investment needed to upgrade the freezers and the undesirable color, taste and aroma of tuna that has been frozen for over two months, the U.S. seafood industry has been limited to using fresh seafood for sashimi and either fresh or frozen seafood with an undesirable' color and flavor for cooking.

### 3. Benefits of Conventional Smoke and Tasteless Smoke

The components in conventional smoke fix the color of the seafood by reacting with the myoglobin to form compounds that are more stable at conventional frozen temperatures than oxymyoglobin. The carboxymyoglobin, nitric oxide myoglobin and nitrogen dioxide myoglobin form when conventional smoke is used to treat seafood. Because these forms of myoglobin are much more stable in a conventional freezer environment than oxymyoglobin, frozen smoked seafood will not experience the browning that is associated with its unsmoked counterpart.

Conventional smoke, however, imparts a characteristic smoke flavor which impacts the taste of the seafood product. The smoke taste makes conventional smoking an undesirable process for preserving the color, taste, texture and aroma of frozen seafood. Tasteless smoke provides a desirable alternative because it offers the preservative benefits of conventional smoke without the conventional smoke taste.

The treatment with tasteless smoke, like conventional smoke, results in the formation of carboxymyoglobin, nitric oxide myoglobin and nitrogen dioxide myoglobin. Unlike oxymyoglobin, these compounds are more stable in a frozen environment and do not lead to the formation of metmyoglobin or facilitate the oxidation of unsaturated fatty acids which generate off odors. It is important in cold smoking to keep the meat raw and uncooked to maximize the amount of vital cells available for this reaction.

For example, salmon that is cold smoked using purified wood smoke and vacuum packed can be refrigerated **for** several months without any decomposition or development of off odors. Similarly, tasteless smoke treated tuna can be frozen for several months without any decomposition or undesirable "freezer" smells. The organoleptic "sniff test" shows significant retardation of decomposition of cold smoked product high in carboxymyoglobin.

### B. Tasteless Smoke Has a Preservative Effect on the Taste and Texture of Frozen Tuna

One of the most important qualities of a food is its taste. Texture and aroma are primary attributes of taste and tests have demonstrated that tasteless smoke has a preservative effect on the texture and aroma of treated products.

#### 1. Tasteless Smoke Preserves Texture

Tasteless smoke has been demonstrated to increase the tenderness of raw and cooked tuna that have been frozen and thawed when compared to untreated frozen and thawed tuna. Dr. Maga states that:

> Toughness deals with resistance of fibular protein to cutting where as firmness deals with resistance to pressure, including setting back. Cooking will denature protein making it tougher. More protein/myoglobin denaturation would occur in untreated flesh than treated thereby influencing toughness. Tenderness would be considered to be its attribute because it would be associated with product juiciness.

Dr. Maga performed the texture analysis by using an Allo-Kramer shear press to measure textural properties of random samples from within each group for both raw and cooked (broiled) product. Three groups were tested: **(1)** tuna treated with tasteless smoke, (2) tuna treated with raw smoke, and (3) untreated tuna. The tuna were frozen and stored for either two or six months. The larger the number, the tougher the product. Conversely the smaller the number the more tender the product. 16/ The following table summarizes these results:

**Texture Results for Raw and Cooked Tuna**

| | Frozen for 2 Months | | Frozen for Six Months | |
|---|---|---|---|---|
| | **Raw** | **Cooked** | **Raw** | **Cooked** |
| Untreated | 6.91 | 7.23 | 6.53 | 6.90 |
| Tasteless Smoke Treated | 6.60<br>6.33 | 6.98<br>6.57 | 6.28 | 6.63 |
| Conventional Smoke | 6.37 | 6.60 | **N.A.** | **N.A.** |

**N.A.** = Not **Analyzed**

161 Appendix 6 contains the test results.

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These results show that tasteless smoke treated samples were consistently more tender and juicy, both raw and cooked, than the untreated samples in both two and six month tests. In addition, there was no apparent difference in raw and cooked texture between the raw smoke and tasteless smoke treated samples further demonstrating that tasteless smoke and conventional smoke have comparable effects on texture.

### 2. Tasteless Smoke Preserves Aroma

Dr. Maga measured aroma intensity and did not attempt to distinguish between off-odor (fishy) or desirable aromas. He utilized a trained ten-member sensory panel of six females and four males in an age range of 19 to 58. This group scored raw and cooked (broiled) samples on a 10-point aroma intensity scale with one being bland and 10 being strong. 17/ The following table and chart summarize these results (lower numbers are considered more desirable):

**Aroma Results for Raw and Cooked Tuna**

| | **Frozen for 2 Months** | | **Frozen for Six Months** | |
|---|---|---|---|---|
| | **Raw** | **Cooked** | **Raw** | **Cooked** |
| Untreated | **6.00** | 6.88 | **7.50** | 9.00 |
| Tasteless Smoke Treated | **5.25**<br>**5.33** | **6.13**<br>**6.33** | **6.25** | **7.25** |
| Conventional Smoke | **5.33** | **6.33** | N.A. | N.A. |
| Carbon Monoxide | 5.00 | 6.00 | **6.50** | **7.75** |

**N.A.** = Not **Analyzed**

These results show that the aroma of the untreated samples were consistently stronger both raw and cooked than the aroma of samples treated with carbon monoxide and tasteless smoke in both two and six month tests. Furthermore, there was little difference between raw smoke and tasteless smoke treated samples. In all cases cooked samples had a stronger aroma intensity than raw samples.

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17/ *See* Appendix 7 for the test results.

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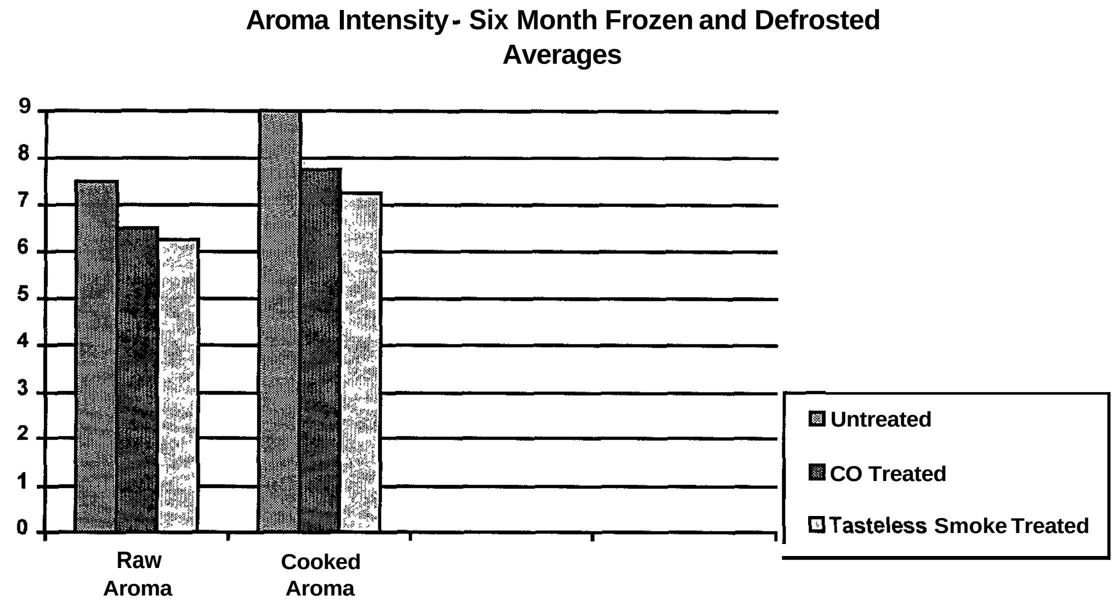
Interestingly, as illustrated by the chart below, the aroma of six month samples treated with carbon monoxide was considerably stronger both raw and cooked than the aroma of six month samples treated with tasteless smoke.




This is a shift from the two month samples in which the carbon monoxide treated samples had a lower aroma, although to a much lesser degree. These data indicate a unique property of tasteless smoke in better preserving aroma during longer term frozen storage. Tasteless smoke treatment, therefore, influences tuna aroma differently than either carbon monoxide treatment or no treatment and has a preservative effect by preventing the development of strong fish odors during freezing. It is postulated that these preservative effects are due in part by preventing the oxidation of the iron ion in the myoglobin. 18/

C. Antimicrobial and Antioxidative Properties **of** Tasteless Smoke

Tasteless smoke also offers anti-microbial and antioxidative properties. Preservation results both from a reduction of microbial counts during smoking and an extension of the shelf life of the treated fish. Conventional smoke contains numerous compounds with antioxidant-properties such as pyrocatechol, hydroquinone, guaiacol, eugenol, isoeugenol vanillin, salicylaldehyde, 2-

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18/ *See also* Judge, Aberle, Forrest, Hedrick and Merkel, "Principles, of Meat Science" (undesirable odors can be prevented by immobilizing the iron atom in myoglobin).

000111

hydroxybenzoic acid, and 4-hydroxybenzoic. 19/ These antioxidative phenolic derivatives will retard lipid-associated rancidity in seafood.

According to Dr. Maga, "any phenolic that can produce a quinid structure will demonstrate some de'greeof [antioxidative] functionality." 20/ Tasteless smoke contains aromatic phenols, albeit at concentrations below the taste and odor threshold, and they will demonstrate antioxidative functionality.

Tasteless smoke also has a preservative effect by lowering the pH of the fish. The carbon monoxide and carbon dioxide in the tasteless smoke react with the water naturally present in the seafood to form carbonic acid. Even small pH changes can be significant and result in an increase in shelf life. A study analyzed the effect of tasteless smoke on the **pH** of seafood and the results are summarized in the table below. 21/

| **pH of Seafood Frozen for Two Months** | |
|---|---|
| Untreated | 5.97 |
| Tasteless Smoke Treated | 5.95 |
| Conventional Smoke Treated | 6.10 |
| Tasteless Smoke Treated | 6.06 |

These data show that, in all cases among species, each tasteless smoke treated sample was more acidic than either an untreated sample or a conventionally smoked sample cut from the same fish.

## D. Tasteless Smokes Fixes Color

Tasteless smoke also has a preservative effect in that it maintains the color of the seafood during frozen storage. Tasteless smoke "fixes" the color of tuna and other red-meat seafood in the same way that nitrates and nitrites fix the color

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**19/** Toth, *"Smoke-related **phenolic compounds with proven antioxidative properties,"*** Advanced Food Rest., 29, 87, (1984).

20/ Maga, *"Smoke **in** Food **Processing,"*** Chapter 7.

21/ ***See*** Appendix 8, "pH Measurements Tests."

000112

of cured meats (*i.e.*, by reacting with the myoglobin to form compounds other than oxymyoglobin).

Just as the resulting color of pork treated with nitrates differs slightly from the uncured color, the color of red-meat seafood treated with tasteless smoke differs slightly from the untreated color. 22/ The difference in color is primarily attributable to an increase in the yellowness of the sample, although there are also subtle differences in the redness and lightness. The slight yellowing of treated seafood parallels a slight increase in the yellow component of untreated seafood that occurs naturally during the freezing and thawing process.

An independent laboratory measured the effect of tasteless smoke on the color of tuna and other red-meat seafood. Using a Hunter Lab Color Difference Meter, the laboratory measured the lightness, yellowness and redness of **147** samples of untreated, tasteless smoke treated, and carbon monoxide treated fish that had been frozen and stored for either six or two months. The laboratory measured the color of the samples after they had been thawed in a refrigerator for **24** hours. The same samples were then placed in household resealable bags and held at 4°C for five days and the color measurements were repeated.

The samples were taken from yellowfin, bigeye, and albacore tuna, and salmon of varying sizes and grades typically used to produce products for the U.S. market. The color properties of five fresh chilled tuna (three yellowfin and two bigeye) of varying weights and grades were also tested to demonstrate the impact of tasteless smoke on the color of the product. 23/ The results from the analysis are summarized below:

### 1. Lightness

Lightness values, which measure the intensity of the color, were lower for tasteless smoke treated frozen and defrosted tuna samples than for either carbon monoxide or untreated frozen and defrosted samples. The tasteless smoke treated samples had the lowest color "intensity" ratings of the previously frozen 'samplestested.

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22/ ***See*** Appendix 9, "Untouched Color Photographs," which shows the color of treated and untreated samples.

**23/** See Appendix **5,** "Data of Color Properties Test Results," for the color test results.

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| Product | Lightness | |
|---|---|---|
| | **Day 1** | **Day 5** |
| Fresh Tuna | 80.26 | **N.A.** |
| Untreated Tuna (Frozen 2 Mths) | 80.55 | 81.10 |
| Tasteless Smoke Treated (Frozen 2 Mths) | 80.49 | 80.72 |
| CO Treated (Frozen 2 Mths) | 80.74 | 80.88 |

### 2. Yellowness

**A** natural "yellowing"occurs in frozen and defrosted untreated tuna and other species as evidenced by a 58 percent increase in yellowness values. The treatment with tasteless smoke does not prevent this "yellowing"as the yellowness value of the tuna steak continues to increase for the tasteless smoke treated product during storage at frozen temperatures. The frozen and thawed tasteless smoke treated sample is slightly more yellow in color than the untreated frozen and thawed sample and significantly more yellow than the untreated fresh sample.

| Product | Yellowness | |
|---|---|---|
| | **Day 1** | **Day 5** |
| Fresh Tuna | +0.50 | N.A. |
| Untreated Tuna (Frozen 2 Mths) | +0.79 | +0.38 |
| Tasteless Smoke Treated (Frozen 2 Mths) | +0.85 | +0.50 |
| CO Treated (Frozen 2 Mths) | +0.95 | +0.83 |

### 3. Redness

The redness of tuna is an important characteristic because a darker, redder color is considered more desirable **by** consumers. The following tables summarize test results for carbon monoxide treated, tasteless smoke treated and untreated yellowfin and bigeye tuna steaks that had been frozen for two months. These frozen samples were thawed and their red color was compared to that of fresh tuna steaks.

| Comparison of Average Redness Values for Frozen and Thawed Tuna (1 and 5 Days) with Fresh Tuna | | |
|---|---|---|
| **Product** | **Redness** | |
| | **Day 1** | **Day 5** |
| Fresh Tuna | **1.76** | N.A. |
| Untreated Tuna (Frozen 2 Mths) | **0.48** | **0.31** |
| Tasteless Smoke Treated (Frozen 2 Mths) | **1.70** | **1.47** |
| CO Treated (Frozen **2** Mths) | **2.15** | **2.00** |

After two months of frozen storage and **24** hours of thawing, tasteless smoke treated tuna has an average redness measurement of **1.70** which is approximately the same as the **1.76** average measurement for the fresh untreated tuna fillet. (The average redness is also **1.70** for tasteless smoke treated tuna that have been frozen for six months and thawed.) The carbon monoxide treated tuna average score of **2.15** shows that carbon monoxide, unlike tasteless smoke, substantially increases (*i.e.* by **24** percent) the redness of tuna steaks. The untreated sample had the lowest redness ratings which demonstrates the adverse impact that two months of freezing has on the redness of tuna. These results are summarized in the chart below:

000115



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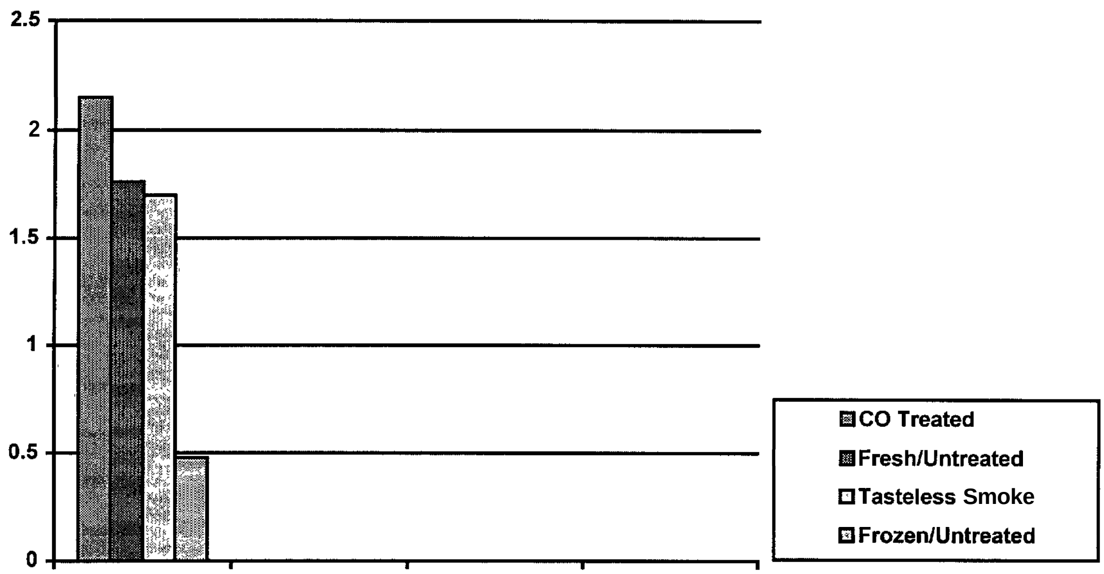
Red Color Values - Day One
Yellowfin and Bigeye Tuna




The redness of the tasteless smoke treated product, however, declines once the product is thawed. The average redness measurement for tasteless smoke treated tuna declines **14%** over five days of refrigeration while the average measurement for carbon monoxide treated tuna declines 7% over the same period. This carbon monoxide treated tuna still remains in an enhanced state **14%** redder on its fifth day than fresh tuna on its first day. While individual sample measurements will vary with species and grade, the overall average of a large sample size will consistently show carbon monoxide treated tuna at an enhanced level of redness and tasteless smoke treated tuna at a comparable level of redness to fresh tuna.

Dr. Maga concludes in his report on color measurement that:

> all carbon monoxide treated samples were redder in color than untreated and tasteless smoke treated samples, with the untreated samples the darkest in color. With storage, the carbon monoxide treated samples held more red color, the untreated samples lost the most color, and the tasteless smoke treated samples were in between.

He adds that there were "some differences among fish types, no differences between fish loins or fish fillets..." The data also showed that higher grades of fish displayed higher color values.

000116

These test results show that treatment with tasteless smoke as applied "fixes" the red color characteristic at its fresh level until thawing at which point a natural fading occurs during refrigerated storage. Treatment with carbon monoxide "enhances" the red color characteristic of equivalent samples throughout the freezing, thawing, and storing process until used with less degradation of this enhanced color.

Tasteless smoke also has the same general effect on salmon. These data show that without tasteless smoke treatment the color degrades in the frozen state and continues to fade more rapidly after thawing than tasteless smoke treated samples. Thus, using the same ingredient and means of treatment for salmon as tuna produces the same results of color "fixing" and preservation.

**Redness Results for Salmon (Compared to Fresh/Unfrozen)**

| | **Thawed 1 Day** | | | **Thawed 5 Days** | | |
|---|---|---|---|---|---|---|
| | **High** | **Low** | **Avg** | **High** | **Low** | **Avg** |
| Untreated | **3.20** | **3.10** | **3.15** | **2.80** | **2.70** | **2.75** |
| Tasteless Smoke Treated | **4.00** | **3.50** | **3.75** | **3.80** | **3.30** | **3.55** |
| Carbon Monoxide Treated | **4.40** | **4.30** | **4.35** | **4.20** | **4.20** | **4.20** |

### E. Tasteless Smoke Has the Same General Effect on Color as Conventional Smoke

Tasteless smoke has the same general effect on the color of seafood as conventional smoke. Dr. Maga used the Hunter Lab Color Difference Meter to test the hypothesis that raw smoke and tasteless smoke behave similarly as ingredients in the treatment of seafood. These results, as illustrated in the chart below, consistently showed the raw smoke treated samples to be redder than the super-purified tasteless smoke treated samples for all species. 24/

24/ *See* Appendix **10,** for the test results.

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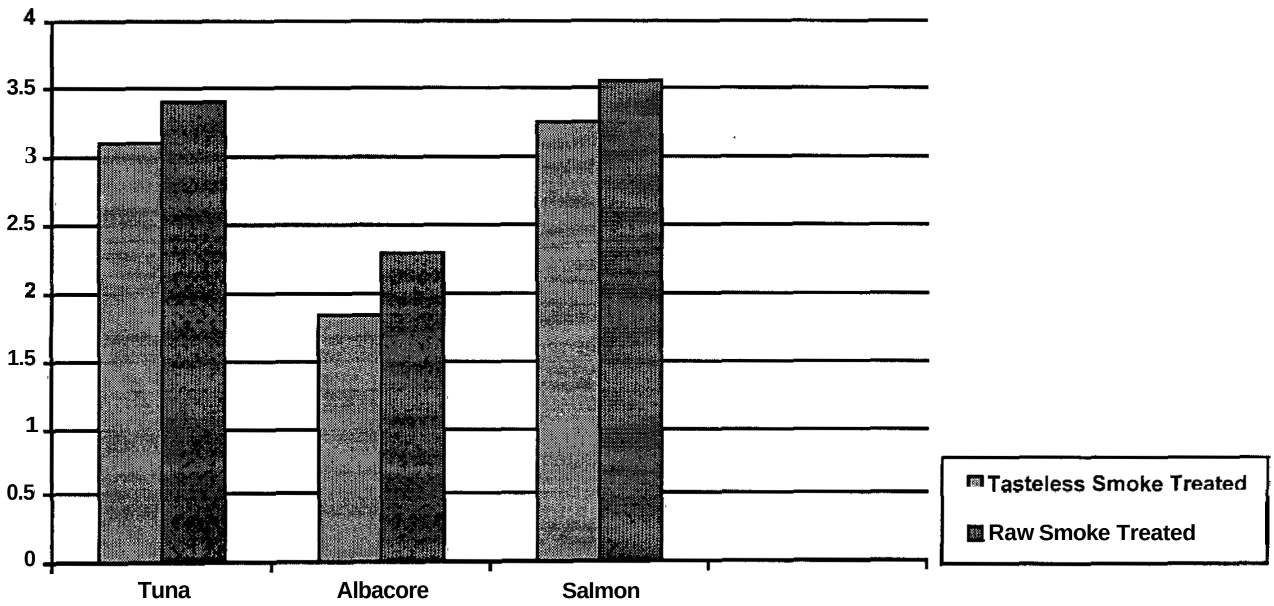
Red Color Values - Day One
Raw Smoke vs. Tasteless Smoke




The results further showed a natural fading of red color over the five day storage period for both raw smoke and tasteless smoke treated samples as illustrated in the chart below.

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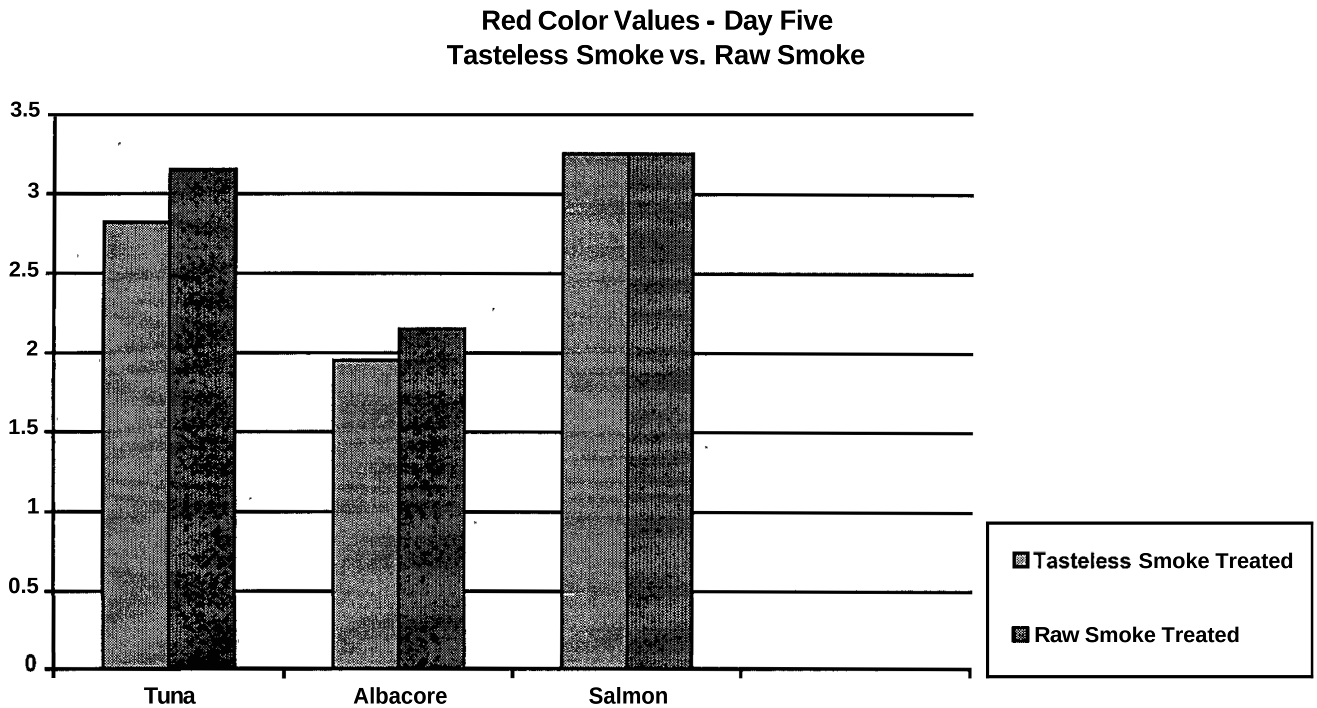


These tests used a higher grade of tuna, Japan "A" grade, than the other tests which used a Japan "B" grade or "#1" cooking grade. The higher grades of tuna have more vital myoglobin cells which would more easily discern any differences between raw smoke and tasteless smoke. The comparison of raw smoke with super-purified tasteless smoke treated samples shows that super-purification does not increase color imparting attributes from raw smoke levels. On the contrary, "super" filtering reduces somewhat the color imparting attributes of the resultant tasteless smoke from raw smoke levels.

### F. Tasteless Smoke is Different than Carbon Monoxide

During the summer of 1997, the Office of Seafood at FDA released a letter to the seafood industry in which the agency took the position that carbon monoxide could not be used in the treatment of raw tuna because it is an unapproved food additive and because it economically adulterates the product. Since issuing that letter, Hawaii International Seafood has met with individuals in the Office of Seafood to clarify the distinctions between tasteless smoke and carbon monoxide. As part of that meeting, FDA asked for data demonstrating that carbon monoxide and tasteless smoke have a different functional effect when added to food. The following studies, in addition to the color studies discussed previously, establish that this is the case.

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### 1. Tasteless Smoke Has a Different Effect on the Color of Tuna than Carbon Monoxide

Samples of yellowfin and albacore tuna were treated with tasteless smoke, treated with carbon monoxide, and frozen and thawed. An independent laboratory convened a focus group which was asked to rate the quality of various characteristics 24 hours after thawing and 72 hours after thawing. 25/

The focus group reported that 24 hours after thawing, the carbon monoxide treated yellowfin was rated "bright unnatural red" while the tasteless smoke treated yellowfin was "natural red" and not as bright as carbon monoxide treated. After 72 hours, the carbon monoxide treated yellowfin was "slightly faded, but still bright unnatural red," while the tasteless smoke treated yellowfin was "slightly faded no longer a sashimi red."

There is little change in color of yellowfin tuna treated with tasteless smoke compared with its fresh untreated state, while there is a substantial bright unnatural red-pink color of the same tuna treated with carbon monoxide. Further, the tasteless smoke treated yellowfin and albacore tuna fade naturally with time after thawing while the carbon monoxide treated samples retain substantially all of the bright unnatural color.

### 2. Tasteless Smoke Treated Tuna Has a Different Taste Than Carbon Monoxide Treated Tuna

Raw and cooked tasteless smoke treated yellowfin and albacore tasted similar to fresh after thawing. Raw carbon monoxide treated yellowfin and albacore exhibited a flat "plastic" taste, while cooked carbon monoxide treated product did not have much flavor. Those in the focus group panel by far preferred the cooked tasteless smoke treated yellowfin as the best of all the samples exhibiting a rich, full fresh-like taste.

### 3. Tasteless Smoke Treated Tuna has a Different Texture Than Carbon Monoxide Treated Tuna

The focus group panel was asked to rate the firmness, or resiliency, of the samples. Here the untreated sample displayed significant softness and moisture loss after thawing. By comparison, the carbon monoxide treated samples were very firm with little moisture loss and the tasteless smoke treated samples were slightly softer with more moisture loss. After three days the carbon monoxide treated samples were still firm while the untreated and tasteless smoke treated samples were softer. The tasteless smoke treated tuna retained more of the

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25/ *See* Appendix **11,** for the test results.

firmness of fresh tuna than the untreated tuna, yet degraded naturally after thawing.

### 4. Tasteless Smoke Treated Tuna Has Less Residual Carbon Monoxide in the Flesh Than Carbon Monoxide Treated Tuna

As discussed earlier, seafood treated with raw smoke or tasteless smoke has myoglobin molecules with open receptors that undergo a chemical reaction with a variety of compounds present in the smoke--carbon monoxide, nitrous oxide, nitrous dioxide--that stabilizes the myoglobin iron and keep it from oxidizing. Different species, and different grades of different species, have different amounts of vital myoglobin cells available for such reactions. This can be viewed as the capacity, or potential for color reaction. Species and grades with a higher capacity will have proportionately higher saturations. This is readily apparent in the grading of fresh tuna. The greater the number of myoglobin molecules, the greater the capacity for oxygen color reaction as oxymyoglobin. The more the saturation of oxymyoglobin, the redder the fresh meat.

Treatment with either chemical carbon monoxide gas or tasteless smoke will result in a saturation of a portion of the capacity for color reaction of the myoglobin molecules into carboxymyoglobin. It is not possible to establish a maximum level of residual carbon monoxide per kilogram of fish since carbon monoxide saturation will be higher for higher grades and for certain species given identical treatment procedures. However, it is possible to compare residual carbon monoxide levels of chemical carbon monoxide treated versus tasteless smoke treated identical samples. 26/

**Residual Carbon Monoxide Levels**
**(micrograms per kilogram)**

| | Lab 1 | | | Lab 2 | | |
|---|---|---|---|---|---|---|
| | High | Low | Avg | High | Low | Avg |
| Untreated | 49 | 30 | 39 | 56 | 8 | 29 |
| Tasteless Smoke Treated | 1400 | 400 | 768 | 416 | 101 | 243 |
| Carbon Monoxide Treated | 2100 | 240 | 1142 | 682 | 76 | 371 |

26/ *See* Appendix 12, "Residual CO Level Test Results," for the data.

On an absolute level the measurements by the laboratory number 1 are 2.5 times higher than the measurements of laboratory number 2. These differences may be attributable to equipment, testing procedures, and/or the capacity of the varying grades and species. More importantly, on a comparative level, both laboratories showed that carbon monoxide treated tuna showed about 50 percent higher average residual carbon monoxide levels than tasteless smoke treated tuna.

## G. Other Benefits of Tasteless Smoke Treated Tuna

### 1. The Use of Tasteless Smoke Enables the Food Industry to Comply with Public Health Recommendations

There is an increasing concern among FDA and other public health authorities regarding the safety of consuming raw, unprocessed seafood because of possible parasite infestation. The 1997 Food Code requires raw, marinated, or partially cooked fish to be frozen to ensure destruction of parasites. The Food Code specifies that the fish should be frozen throughout at a temperature of -20°C for seven days or - 35°C for 15 hours in a blast freezer. The Food Code is a model code published by FDA that is intended to serve as the framework for local and state ordinances regarding the handling of food in restaurants and retail stores. Although the Food Code is not a federal law, some state and local jurisdictions incorporate all of its provisions into their statutes and ordinances.

Implementing the Japanese method of super cold freezing (-76°F or less) (-60°C or less) and storage to preserve color and kill parasites is impractical in the U.S. because of the retrofitting and capital investment required. It would cost millions of dollars to add super cold freezers to every cold storage facility, seafood distributor facility, restaurant, sushi bar, and supermarket across the U.S. Because of this high cost relative to the size of the U.S. market, super freezers are not a practical solution.

It is our understanding that many sushi establishments and other restaurants that serve raw fish dishes are reluctant to comply with the 1997 Food Code recommendation because frozen fish frequently lacks the taste, texture and appearance of fresh fish. The tasteless smoke treated product, however results in a product that is comparable in taste, texture, appearance and overall palatability to the non-frozen tuna. The use of tasteless smoke, therefore will prove valuable in helping restaurants comply with the 1997 Food Code and with the recommendations of FDA and other public health officials regarding the freezing of seafood that is to be consumed raw.

### 2. Tasteless Smoke Has Economic Advantages

The consumer is also receiving an economic benefit because frozen tuna steaks are much less expensive than fresh steaks primarily due to the cost differences between air freight and ocean freight. Fresh fish is typically air freighted from Pacific fisheries to the U.S. on ice in H & G form (whole with the head and gills removed). The average cost of such air freight is $1.92/lb. Generally, 53% of this fish will be lost during filleting so the per pound air freight, where calculated on the basis of the edible tuna, increase to $4.09/lb. In contrast, the tasteless smoke treated products are cut into steaks or fillets near the Pacific fisheries and treated with the tasteless smoke and frozen. The frozen fillets and steaks are shipped via ocean liners to the U.S. at a cost of about $0.19/lb. Although the tasteless smoke technology will add some costs to the raw tuna, the savings in air freight far exceeds these costs, so the economic savings could be passed onto the consumer in the form of lower seafood prices.

For example, fresh Indonesian tuna is delivered to master distributors in the U.S. at an average price of $3.35/lb. It will cost each U.S. distributor approximately $.17/lb. of H & G tuna to fillet into steaks. After filleting loss of 53% of the unused fish, the yielded fresh steak cost is $7.50/lb. Hawaii International Seafood, Inc. will deliver the exact same grade of frozen tuna steak, treated with tasteless smoke, for $4.95/lb. to the master distributor. This is a savings to the consumer of $2.55/lb. at the master distributor level.

In addition, the retailer has the added benefit of being able to stock frozen inventory and thaw out only what is needed on demand, thus avoiding the degeneration of quality associated with aging fresh seafood. This allows the retailer to maintain a consistent, high quality, "previously frozen" tuna steak supply available for his customers while reducing losses to spoilage.

## IV. METHODS FOR DETECTING THE SUBSTANCE IN FOOD

There is not a method for detecting the presence of the ingredient tasteless smoke in food. There are methods, however, which can be used to detect for the presence of the components of tasteless smoke, such as the nitrogen, oxygen, carbon monoxide, carbon dioxide, aromatic phenols and hydrocarbons. These methods are as follows:

| Component: | Method Number | Abbreviated Method Name |
|---|---|---|
| Carbon Dioxide | ASTM D1946 | Analysis of Reformed Gas by Gas Chromatography (GC) with Thermal Conductivity Detection (TCD) |

| | | |
|---|---|---|
| Carbon Monoxide | ASTM D1946 | Analysis of Reformed Gas by Gas Chromatography (GC) with Thermal Conductivity Detection (TCD) |
| Aromatic Phenols (gaseous vapor) | EPA TO-8 | Phenols and Cresols in Ambient Air by High Pressure Liquid Chromatography HPLC |
| Hydrocarbons ($C_5$ to $C_{10}$) | EPA **TO-14** | Volatile Organic Compounds in Ambient Air by GC/FID (flame ionization detection) |
| Hydrocarbons ($C_2$ to $C_4$) | EPA **TO-14** | Volatile Organic Compounds in Ambient Air by GC/FID |

## V. CLAIM OF CATEGORICAL EXCLUSION FROM THE ENVIRONMENT ASSESSMENT

Hawaii International Seafood claims a categorical exclusion from the environmental assessment (EA) and environmental impact statements (EIS). Under the recently finalized environmental impact consideration regulations, actions involving "the approval of food additive, color additive, or GRAS petitions for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in the food," ordinarily do not require the preparation of an EA or EIS. 27/

FDA clarified in the preamble to the proposed rule that "[e]xamples of the types of additives and GRAS substances that belong to this class are the color additives added to foods listed in **21** CFR parts **73** and **74,** most of the direct food additives listed in part **172 (21** CFR parts **172)**, and certain GRAS substances listed in part **184** (21 CFR part **184.).**28/ FDA further offered that "examples of substances not included in this class for which this categorical exclusion is being proposed are the substances intended to replace macronutrients in food (such as sweetening agents intended to replace sugar ***e.g.,*** see §§ **172.800** and **172.804,** and fat substitutes ***e.g.,*** **184.1498."**29/

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27/ 62 ***Fed. Reg.*** **40570, 40595 (1997)** (to be codified at **21** CFR § 25.32(k) **(1998)).**

28/ **61 *Fed. Reg.* 19476, 19482 (1996) *(emphasis added).***

291 ***Id.***

Although the GRAS premarket notification proposed rule would not require an environmental assessment, the GRAS affirmation petition regulations do require one. Because the agency has not yet issued the final rule that would establish the GRAS premarket notification procedures, Hawaii International Seafood submits a request for a categorical exclusion.

This GRAS premarket notification complies with the categorical exclusion criteria in 21 CFR § 25.32(k) (1998). Tasteless smoke is a direct food ingredient that is intended to remain in the food through ingestion, and it is not a macronutrient. In addition, to the knowledge of Hawaii International Seafood, there are no extraordmary circumstances that would refute this categorical exclusion.

# HOGAN & HARTSON
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February 9, 2000

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***BY FACSIMILE AND REGULAR MAIL***

George Pauli, Ph.D.
Director of the Division of Product Policy .
Office of Premarket Approval
Center for Food Safety and Nutrition
Food and Drug Administration
200 C. Street SW (HFS-205)
Washington, D.C. 20204

**Re: GRAS Notification for Tasteless Smoke**

Dear Dr. Pauli:

Pursuant to our telephone conversations'of February 8th and 9th, we are asking the agency to limit its review of the aforementioned GRAS notification to the use of tasteless smoke on tuna. We filed the GRAS notification for tasteless smoke on behalf of Hawaii International Seafood Inc., International Seafood Inc., Honolulu International Airport, P.O. Box 30486, Honolulu, Hawaii 96820, on March 11, 1999. Although the original notification covered the use of tasteless smoke on numerous species of seafood, including salmon, we are asking the agency to limit its review to the use of tasteless smoke on tuna.

Hawaii International Seafood continues to believe that tasteless smoke is GRAS when used on other species of seafood. The client reserves the right to submit future notifications that would cover the GRAS status of tasteless smoke on species other than tuna. Such notifications would include the type of information that we discussed during our telephone conversations, particularly with regard to efficacy data demonstrating that tasteless smoke is a preservative and/or color fixative when used on species other than tuna.

If you have any questions, please feel free to contact me.

Sincerelv.

Martin J. Hahn \

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